IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

SECURITY NATIONAL BANK, as Conservator for JMK, a minor child,	No. C11-4017-MWB
Plaintiff,	Sioux City, Iowa January 7, 2014
vs.	8:20 a.m.
ABBOTT LABORATORIES,	Volume 2 of 10
Defendant.	

REDACTED TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE MARK W. BENNETT
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff:	AMANDA BRANDY VAN WYHE, ESQ. TIMOTHY S. BOTTARO, ESQ. Vriezelaar, Tigges, Edgington, Bottaro, Boden & Ross 613 Pierce Street Sioux City, IA 51102 STEPHEN C. RATHKE, ESQ. ROBERT J. KING, ESQ. Lommen, Abdo, Cole, King & Stageberg 2000 IDS Center 80 South Eighth Street Minneapolis, MN 55402
For the Defendant:	JOHN C. GRAY, ESQ. Heidman Law Firm 1128 Historic 4th Street Sioux City, IA 51102 DANIEL E. REIDY, ESQ. JUNE K. GHEZZI, ESQ. GABRIEL H. SCANNAPIECO, ESQ. KATHRYN L. DORE, ESQ. Jones Day Suite 3500 77 West Wacker Drive Chicago, IL 60601
Also present:	Louise Deitloff Daniel Morrison
Court Reporter:	Shelly Semmler, RMR, CRR 320 Sixth Street Sioux City, IA 51101 (712) 233-3846

(Proceedings reconvened outside the presence of the jury.)

THE COURT: Anything we're going to need to take up?

MS. GHEZZI: Judge, June Ghezzi for the record. I just want to note that I believe that it's fine for an expert witness to talk about the slides, of course, but I think that what we have is Dr. Jason has the slides and then she has notes written all over it, you know, annotated, handwritten notes that I think she's going to use. I don't -- I mean, we would object to that.

THE COURT: On the -- I just want to make sure I understand. They're going to put slides up, and she has notations on the slides?

MS. GHEZZI: I don't think they're going to put up the slides with her notations. I think she's going to testify from her notations on the slides that she has with her in the courtroom at the witness stand.

THE COURT: So she's made notes on a set of slides.

MS. GHEZZI: It looks that way.

THE WITNESS: If you could --

THE COURT: Okay. Educate me. What's wrong with that?

MS. GHEZZI: Well --

THE COURT: I think you're entitled to see it, but what's impermissible about a -- I mean, expert witnesses bring

in entire files all the time with all kinds of handwritten notes and typed notes and reports.

MS. GHEZZI: Well, I mean, Judge, my experience is is that the expert witness can bring in her report or his report. I mean, if --

THE COURT: They can bring in anything they relied on, and they can bring in stuff they didn't rely on. You're entitled to see it, but you tell me a rule or case that says they can't have anything they want in front of them. You're entitled to see it.

MS. GHEZZI: Right.

THE COURT: So you can cross-examine them on it.

MS. GHEZZI: No, it's just a question of can they testify -- are they testifying from their memory at the time that they're on the witness stand or are they testifying from notes that they're making? If they can testify -- if Your Honor is --

THE COURT: Well, they can be -- you can have a past recollection recorded refr -- you know, so -- I've never heard of anything impermissible. And I just may be missing something.

MS. GHEZZI: Okay.

THE COURT: But I'm interested in being educated about it.

MS. GHEZZI: I'm just saying that they haven't established that she can't remember what she's going to talk

about without her having notes in front of her. So it's not -- you know, if she can't remember, then maybe you can show her something. Certainly she can have whatever documents or he can show her whatever documents she relied on to form her opinion in the case. But if she's doing handwritten notes now for trial and she's going to testify from her handwritten notes, she's not relying on those handwritten notes to form her opinion in the case. She's writing notes now to help her testify. That's --

THE COURT: How is that any different than what's on the PowerPoint slides?

MS. GHEZZI: I assume that it's more information than what's on the PowerPoint slides which we don't --

THE COURT: Well, if they put that information -- actually write on the slides, it wouldn't be objectionable.

MS. GHEZZI: It may not be, but I don't know what it is. There are 64 slides.

THE COURT: See, that's the point. You don't know what it is. That's why you have a right to see it and you can cross-examine her on it. But it's not because she has handwritten notes on the slides that make it impermissible because they could have added that text to the slides and put it up.

MS. GHEZZI: Sure.

THE COURT: So I think the issue is you have a right to examine what she's testifying from and cross-examine her on

it.

MS. GHEZZI: Okay.

THE COURT: And I will let you do that.

MS. GHEZZI: I think Dr. Jason's the only one who's got copies of --

THE COURT: Yes, and she'll have to give that to you when she's done, and then you can cross-examine her on it if you want to.

MS. GHEZZI: Okay, Your Honor. I mean, that's fine.

THE COURT: Okay.

MS. GHEZZI: Thank you.

THE COURT: Thanks.

MR. BOTTARO: Judge, I also forgot to mention to you that Nancy Clearwater from our office will play the part of Sharon Bottock, so it's Nancy Clearwater, just the way it sounds spelling, and Bottock. Thank you.

THE COURT: Okay.

MR. SCANNAPIECO: Your Honor, quick question.

THE COURT: Yes.

MR. SCANNAPIECO: Is there going to be a little break between the direct and the cross for Jason so we can -- we need to move our computer up in between the two.

THE COURT: Yeah, there will be like a stretch break.

MR. SCANNAPIECO: Just one of those couple-minute breaks?

THE COURT: Yeah.

MR. SCANNAPIECO: Okay.

THE COURT: Can you do it in a minute -- what do you need to do?

MR. SCANNAPIECO: We just need a couple minutes once it starts just to test it on the screen. I can have it plugged in.

THE COURT: Well, can't you have it all ready to go and then just hit the source button? You understand what I mean? You have your computer all set to go. You have it on. You have it set to where you need it, and then you just hit the source code -- I'm sorry, not code, the source button.

MR. SCANNAPIECO: Yeah, so we can just --

THE COURT: So it's really just a matter of hitting the button so that it gets displayed there.

MR. SCANNAPIECO: Okay.

THE COURT: Right?

MR. SCANNAPIECO: Yes. I'm just checking.

THE COURT: No, sure. Yeah, but I can -- we can do a stretch break.

MR. SCANNAPIECO: Okay.

THE COURT: So there will be a little bit of time to switch.

MR. SCANNAPIECO: I got everything set as much as I can.

DR. JASON: Sir, I just have a question. Does that mean I can --

THE COURT: Yeah, you can't really be asking me questions.

DR. JASON: I can't do that? Okay.

THE COURT: It doesn't work that way. Sorry. How many depositions were taken in this case just approximately?

MR. RATHKE: That I took.

THE COURT: I don't care who took them. How many depositions -- that wasn't my question. How many depositions were taken in the case?

MR. RATHKE: Twenty maybe.

MR. SCANNAPIECO: I can tell you how many it was. About 15.

THE COURT: Approximately.

MR. RATHKE: Fifteen to twenty.

THE COURT: Well, I want to see all of the depositions that were taken in the case, and so -- it relates to the sanctions. And I'd like to read them all, and so how long will it take you to get me copies of all of the depositions?

MS. VAN WYHE: Printed or electronic?

THE COURT: We can do it in electronic format. That'd be easier for the parties. I'd have to print it out and put them in binders, but that's fine.

Tomorrow? Can I have them by tomorrow?

MR. RATHKE: Oh, sure.
THE COURT: Yeah, that's fine.
MR. RATHKE: Okay.
THE COURT: You don't need to send me the depositions you've already sent me that I've reviewed.
MR. RATHKE: You've got --
THE COURT: But the remaining depositions.
MR. RATHKE: Right.
THE COURT: Okay.
(Recess at 8:27 a.m.)
THE COURT: Okay. Ready to have the jury brought in? Okay.
(The jury entered the courtroom.)
THE COURT: Good morning. Please be seated. As you will recall, we were still on the direct examination of Dr. Jason.

JANINE JASON, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

THE COURT: Mr. Rathke, you may proceed.
MR. RATHKE: Thank you, Your Honor.

CONTINUED DIRECT EXAMINATION

BY MR. RATHKE:

Q. Dr. Jason, are cronobacter infections common?
A. No.
Q. Why aren't they?
A. Well, there are several reasons for that. One is it is not

an organism that we commonly find, at least in terms of the ones that would cause an infection. Could I have slide 17?

There have been studies done to look at where they can isolate cronobacter from. And if you just do cultures and you look hard enough, you can find cronobacter. Enteric organisms are fairly common. I won't say ubiquitous, but they're fairly common. And some examples of this that you'll probably be hearing from the defense are two studies that I would like to go over a little bit.

One was by a person named Kandhai. He did the study back in 2004, and he did it in collaboration with a formula manufacturer.

MS. GHEZZI: Objection, Your Honor. Narrative.

THE COURT: Overruled.

A. And what they did in the study was they did environmental testing both in food environments, food factory environments, and in households. And they did the households in a bit of an odd way. They collected vacuum cleaner bags. So they didn't go into kitchens which is where you usually find enteric bacteria because it is in food. But they took vacuum cleaner bags.

And this was done quite a while ago. It was before this bacteria's name switched to cronobacter, and it was done before the strain typing work was done. So this is a fairly old study.

Could I have the next slide, next slide?

THE COURT: And why don't we have a next question to go with it.

Q. And so what did they find in that study?

A. In that study what they found was that indeed they could find cronobacter in most of the factories, and that included both powdered infant formula factories but also other foods because there are cronobacter in other foods, especially things like cereals and spices. And they did find in about a little bit under a third of the households that there were some form of cronobacters in those vacuum cleaner bags.

That was not terribly helpful because we know there are very few cronobacter that actually can cause serious infections.

Another study was recently done that was more on target with the sort of information that would be very helpful in preventing these infections.

Could I have the next slide? And that was done just very recently. And --

THE COURT: Well, why don't you -- you know, I thought we had this discussion yesterday.

Q. Be sure to -- well, tell me about --

THE COURT: You be sure and ask questions.

MR. RATHKE: Yes. Yes.

Q. Have there been any other studies other than the Kandhai study, more recent studies?

A. Yes. There was a very recent study, and this study was more on target in trying to sort out what cronobacters are where in a household. And what they did was -- and this was not a well-funded study, so it definitely has some very serious limitations. It was a very localized study. It was done at a health department. It was a very select population. So this is in no way representative of all kitchens in the United States, so you have to accept those limits.

But they did go to the kitchen. They did look at a number of areas where people would be wandering around and potentially coming in contact with contamination.

And so this slide goes over some of the areas that they tested and includes things like countertops, refrigerator handles. And in the sinks which is where you find a lot of enteric bacteria -- it doesn't mean you're going to get -- people won't necessarily get contaminated from it because you don't put your hand down in a sink. But it gives you a sense of what's around and about. So they tested the very bottom also of kitchen sinks.

Next slide.

And what they found was --

MS. GHEZZI: Excuse me, Your Honor. Can we have a question before the slide?

THE COURT: I think she's still explaining the study.

A. And so what they did was look at a lot of contact slides --

sites, and they indeed when they tested found not at more than 1 site per kitchen usually but of the 78 kitchens that they tested, somewhere they found a positive sample in 27 percent, so certainly not all over the board, but there were some positive samples.

Next slide.

Okay. The downside is we know nothing about these households. We don't know what they ate. We don't know what food they had in the kitchen. We don't know who the household members were. We do know that these people were all healthy. It wasn't as if they had any infections or diseases. But, for instance, we don't know if they had young infants on powdered infant formula. We don't know if the family ate cereal, so it's very restricted, but what it says is if you look hard enough there will be potentially in a little bit -- a little over a quarter of the households in the kitchen you may find cronobacter one place or another.

Of note in Jeanine Kunkel's case, the -- oh, and again, let me emphasize we don't know what kind of cronobacter these are.

THE COURT: Okay. I'm p -- stop. Members of the jury, I'm going to send you out. I have a matter I need to take up with the lawyers. Sorry to have to do this, but it will just be very short.

(The jury exited the courtroom.)

THE COURT: Please be seated. Mr. Rathke, I don't think you heard what I said yesterday.

MR. RATHKE: I did hear it, and as soon as the witness went to another subject, I immediately --

THE COURT: It's not very difficult. All you have to do is . . .

MR. RATHKE: I'll do my best.

THE COURT: I'm not going to let her just testify on and on and on. You have to ask a question. She was just switching from the study to this case, and there wasn't a pending question about this case. She was talking about the study, so, you know, all you have to do is take the title of the slide and form that into a question and you wouldn't have a problem, but you seem unable to do that.

MR. RATHKE: I'll do my best, Judge. I apologize.

THE COURT: Okay. Bring the jury in.

(The jury entered the courtroom.)

THE COURT: Please be seated. And this way with all this exercise I won't have to put up the Jane Fonda exercise video for you on the breaks so . . .

Mr. Rathke, you may proceed.

MR. RATHKE: Thank you, Your Honor.

BY MR. RATHKE:

Q. Dr. Jason, this lot was a very large lot, and, you know, counsel for the defense pointed out that many children were fed

from that lot. Why is Jeanine the only one who apparently got sick from that lot?

A. The most important factor I believe is that the contamination is clumped, and the material's not grossly contaminated. You're talking about focal points of contamination.

In addition, these -- these products -- this particular product, the NeoSure, is recommended for infants that are zero to 12 months of age. The infants that are at risk are the ones in the first two months of life. They consume very little of the formula in that lot because they're not eating a lot at that age. So you have the vast majority of the formula going to infants who aren't at risk of this infection. So if you will, it's a little bit like Russian roulette. If you're the one unfortunate one who's the right age -- and there probably are host factors. We don't have a good sense of those yet. But host factors are almost certainly not every infant below two months of age is susceptible to this infection.

So I hate the term the perfect storm, but I suppose it fits this. You need a child at the right age with the right characteristics who's unfortunate enough to come upon those small clumps of contaminated material.

Q. Why is a newborn baby more at risk to an E. sak -- for an E. sak infection?

A. Newborns are amazing creatures. They are -- even if

they're full term at birth, they are not in any -- well, we know this. We're parents. They're not fully mature, and it's not just in the obvious ways. When an infant is born, their immune system is not like an older child's or an adult's. It is what we call more proinflammatory. It means the balance between fighting the infection and recognizing your own body is not quite right yet.

Secondly, the cells, it has no memory. It hasn't seen anything, its immune system. So the cells that are used in fighting infections are what we call more primitive cells. They're not specific to a given infection, so they aren't as powerful, so that's one big factor.

The second is their GI tract. When you think about it, it's amazing what happens in a matter of a few weeks. When the fetus -- when the infant's inside the womb, the gastrointestinal tract is completely sterile. It's not moving. There's nothing in it. It's just sitting there waiting to be needed.

And then when the infant goes through the birth process, it picks up some bacteria from the mother on passage through. In general those are very benign, healthy, good, useful bacteria because we need to have bacteria in our intestines. It helps us digest food. We couldn't do it without the help of bacteria.

And if an infant's breastfed, the breast milk has some

incredibly helpful bacteria as well as immune components that are very useful. Ready-to-feed is sterile, so you're pretty much sitting there without a whole lot in there. But in either case the GI system is just beginning to work. So the infant is born. They get their first feeding. They get introduced to bacteria that start colonizing their intestines.

Now, one big difference in infants in the first weeks of life is -- we'll start at the top. First of all, you start having what's called peristalsis which is moving the food through. It takes weeks for that to get coordinated. In one infant, that may happen sooner than another. They may be working fine, and then they get stressed, and it's not moving in a coordinated way, and that movement is what pushes the food out and pushes bad organisms out of the body all the way from the esophagus down through the stomach through the intestines.

Q. So this is how the GI tract develops?

A. Yes.

Q. Okay.

A. And so early on in the stomach, we have stomach acids that break down pathogenic bacteria, virulent bacteria. And our stomach is very acid. A newborn infant, the stomach is not that acid. And, in fact, if you kind of rank it, a normal child and an adult will have a very acid stomach. A breastfed infant --

Q. Who doesn't have an acid stomach? The normal child or the adult?

A. Both, both.
Q. Okay.
A. But when you get down to younger ages, if an infant is fed breast milk, that breast milk is more acid than formulas, so a breastfed infant's going to have a more acid stomach than a formula-fed infant.
Q. How about if the child's formula fed? How does that affect the acidity of the stomach?
A. That is the least acid of all. So you have that gradation that all newborns, again, are less able in their stomach to kill off bacteria that may not be helpful.
Q. If E. sak gets into a baby's intestine, what happens?
A. If it's very early on -- as the intestines develop, there are a couple of things that go on. One is what we call bacterial crosstalk. That's where the beneficial bacteria and the infant's intestines begin to understand that they belong together.

A very young infant, that isn't coordinated yet. So a very young infant's intestines aren't able to tell whether a bacteria is good or bad. The more good bacteria that are in there, the more they basically compete for space with the bad bacteria. But in the first weeks of life, there's not a whole lot going on. Everything is kind of shaking out.

A second big change is their immune cells in the lining of the intestines, those aren't fully developed yet.

And the third very important factor is the intestinal wall has cells that are sitting right next to each other, and there are areas that are called junctions. And in us, those are very intact. They're very solid. Bacteria can't get through.

In a newborn infant who can't tell a good bacteria from a bad bacteria, a bad bacteria is able -- it's called more porous. Basically a bad bacteria's more able to get through those junctions, and when it gets through, it can get into the bloodstream and then get to places in the body where it doesn't belong, in this case usually the brain.

Q. Is an infant's intestines, a newborn's intestines, a good place for E. sak to grow?

A. Sadly, it is a perfect place for it to grow. Cronobacter sakazakii grows best -- by nature and fate, its best growth is at our body temperature. And, in fact, if we become febrile, it likes that even better. Our body --

Q. If we become what?

A. Pardon? If we get a fever.

Q. All right.

A. So this bug, this bacteria, grows best at body temperature.

Secondly, it's sitting in the intestines with all of this food coming down, so if you will, you've got all sorts of nutrition to feed it. I can't think of a better way to grow a bug like this.

Q. Than what?

A. Than to be sitting in a infant's stomach with lots of food coming in and lots of warmth to help it to grow.
Q. Exhibit 78, please. We're going to bring up Exhibit 78. Okay. I'm showing you Exhibit 78. Could you go to page 6. And focus in on -- okay. Do you see where -- where this document on page 6 has the identification of the Infant Formula Council?
A. Yes.
Q. And then --
THE COURT: You could enlarge the exhibit so everybody could actually see it.
Q. Okay. Then would you go to page 4. And do the see on this footnote that it describes the -- call that out -- the members of the IFC?
A. Yes.
MR. RATHKE: No, no, the footnote.
THE COURT: Why don't you remove the markings. Upper corner.
MR. RATHKE: I got it.
THE COURT: Nope, you don't have it.
BY MR. RATHKE:
Q. Do you see where that identifies the members of the International Formula Council?
A. Yes.
Q. Okay. I'd like you to then go to -- on the same page --
MR. RATHKE: Pat, could you bring up under the heading

enterobacter sakazakii, call that out a little bit?
Q. Do you see where it says that a microorganism of particular concern and which can survive in powdered infant formula is E. sak? E. sak is an opportunistic pathogen that poses little risk to healthy term infants. However, in certain highly vulnerable infants, this microorganism can cause serious infections that can present -- or serious infections that can present severe and life-threatening conditions including meningitis. This most commonly occurs in low-birth-weight and immunocompromised infants. Do you see where it says that?
A. Yes.
Q. Do you agree with that statement of the IFC?
A. I agree that it's of concern. I agree that low-birth-weight and immunocompromised infants are greater risk. I very strongly disagree that normal-birth-weight infants are not at risk, that healthy term infants are not at risk.
Q. Do you believe they are?
A. I believe they are, yes.
Q. To -- to what age?
A. Well, there is no absolute, but I can tell you of the cases that I reviewed, all but one case was less -- they were less than two months of age.
MR. RATHKE: Thanks. Clear that, please.
Q. I'm going to go to another subject which is your -- the epidemiology study that you described to some extent yesterday.

Was that peer reviewed?
A. We're talking about my --
Q. Yes.
A. Yes, it was.
Q. And that was in Pediatrics?
A. Yes.
Q. Would you describe the peer review of your article.
A. It was very much the way all peer review is. In peer review, what -- well, what happens when you submit a paper to a peer-reviewed journal is you fill out a submission form. It goes to the editors, and the first thing they do is -- and there's more than one editor at a journal. And they review the paper. They discuss it. They, among themselves, decide whether they think it's of scientific merit and whether it's of interest to their readership because it is a journal.
Q. Okay. And if they decide it's of interest, how do they initiate the peer-review process?
A. They contact reviewers who do research in areas related to the topic and request that -- whether they would be willing to review the article.
Q. Does the author have an opportunity to provide input into the selection of the people that they contact?
A. Well, yes and no. It's like an urban myth. Most peer-reviewed journals, you --
Q. Well, let's talk about your peer review.

A. Okay. Well, in mine -- for Pediatrics, what they do on the form is you can recommend reviewers that you think are qualified to review the paper.
Q. And did you do that?
A. I am sure I did. Well, yes, I probably did.
Q. All right. Do you know who reviewed your article?
A. No. You never know who reviewed your article. You see, the trick to this process is you can also -- you can recommend several people who you think are qualified, and you can also request that several people not be considered because you feel they for reasons outside of science would not give a fair review. What you never know is journals have been known to go ahead and send it to those very people. So it's -- you know, you're taking a gamble, and you never know how it's going to go. But you also never know who ends up reviewing it.
Q. All right. And was your article published?
A. Yes, it was.
Q. Did you receive suggestions as part of the peer-review process from the unknown persons who reviewed it?
A. That's the good side of this process. Yes. I mean, it's very important -- you have to be within a certain word limit, and very often the suggestions are things they want you to say in the discussion. So you're trying to stay within your word limit and make everybody happy. But you get very good input.
Q. And did you get some good input from the reviews?

A. I did, very good.
Q. And the article was published when?
A. November of 2012.
Q. Who is the audience for Pediatrics?
A. Many other people, but basically pediatricians.
Q. And Pediatrics is sponsored -- the journal Pediatrics is sponsored by whom?
A. The American Academy of Pediatrics.
Q. Go to slide 29. What I'd like you to do, Dr. Jason, is using slides 29 and 31 I think is the other one you wanted to use explain the -- what you found in your study. Describe your findings.
A. Would you mind if I show some other slides? This . . .
Q. I'm sorry. Exhibit -- slide 27.
A. I like that one.
Q. Okay. That was my mistake.
A. I know everybody was tired yesterday. I was tired, and you were here a lot longer, so let me remind you of the background of these slides.
Q. Just -- we need to speed it up.
A. Okay.
Q. So just go right ahead into the slide.
A. Okay. What these slides are going to show you are the characteristics of cases that happened before 2004 and after 2004. And the reason I did these analyses was between 2002 and

2004 information was provided to healthcare providers that they should avoid using powdered formula in premature infants in intensive care units, newborn intensive care units.

As I think you saw previously, the message was there was no risk to normal newborns. So I wanted to see whether the characteristics changed after that warning was given.

Q. Okay. Let's go into your findings.

A. So what you see here is the first thing I looked at was age. And what you see is this NS means not significant. And what that means is that the age distribution of the cases before 2004 and after 2004 were not statistically different. So it wasn't that the ages had changed. The at-risk groups were still very young infants.

Q. The age that's in that line is less than one month?

A. Yes.

Q. All right.

A. Basically an average of 83 percent of all the cases over that entire time period were less than a month of age.

In addition to that, 16 percent were less -- were older than a month but less than two months. So virtually every child except for one was less than two months of age.

The second thing I looked at, since the warning was to not use powdered infant formula for infants in NICUs, I wanted to see were the cases happening in the hospital or at home. And what you see is there was a significant change. The second time

period, over half of the cases were occurring at home, and that difference was highly significant. That was highly unlikely to be a chance event. Next --

Q. Before we leave that, the third column, it says P equals 0.007. What do you mean by that?

A. That means the chances that that change would have been just pure out of chance, the likelihood that was due just to pure chance was seven out of a thousand. So it was a very, very low likelihood that this was just a chance.

Q. Okay. Then 26?

A. And again, the warning had been for premature infants, so I wanted to see if that had changed. Now, one thing you see is that it wasn't -- it wasn't like full-term infants weren't at risk even before then even though no one said they were at risk. Almost a quarter of the infants that were infected before 2004 were full-term infants. But after 2004, that proportion went up. And again, it was very significant. So there was a significant shift so that the majority of cases now were in full-term infants rather than premature infants.

Now, preterm infants were still at greatest risk. But full-term infants also were at risk, and they were, relatively speaking, a greater proportion of the cases after 2004. And --

Q. The second line, you've got some BW and a symbol. Could you explain what your -- what that means?

A. The BW is birth weight, and that weight in both grams and

pounds is the cutoff for what's considered -- and realize there are no absolutes here, but it's basically what is considered a normal birth weight. And --

Q. How much is that in ounces?

A. You see that right there. Basically it's about --

Q. Would you say it, though?

A. About five pounds, six ounces.

Q. All right. And then what did you find with respect to your birth weight?

A. Okay. Now, remember the warning to neonatologists was premature, immunocompromised low-birth-weight infants. Well, again, in the earlier time period, there were some normal-birth-weight infants that were infected. In fact, 20 percent of the cases were normal birth weight even though those were not targeted as being at risk. And in the second time period, that went up to 58 percent. So again, it's highly statistically significant that that shift, taking into account the number of cases we're looking at, was not just due to chance.

Q. Okay. Go to Exhibit -- or slide 29. Does slide 29 kind of summarize your findings?

A. It summarizes the nutrition findings.

Q. Right. Tell us about that.

A. Not every infant that I looked at had nutrition information. Early on, the older cases, nobody realized that

this infection was related to nutrition, so early cases didn't have as much information. But in the later years every infant had information on what they received.

There's also not a lot of information on how many children received formula or different types of formula. But the one national information that is available is for the United States what percent of infants at a month of age are exclusively breastfed. So I used that to see how representative cronobacter-infected infants were of the population. And what you see here is in the U.S. as a whole, 46 percent of newborn -- of one-month-olds are exclusively breastfed. If you look at cronobacter cases, it's only 4 percent.

Now, remember, all -- the cronobacter cases are across the world. So if you want to just do a direct comparison of U.S. crono -- invasively infected infants, there's not a single case that was exclusively breastfed in the United States as of 2010.

Q. Go to 31. What does Exhibit 30 -- how does Exhibit -- or slide 31 explain your findings?

A. Okay. This slide shows that of the infants that were infected invasively with cronobacter -- and these by -- these are healthy infants. I chose -- the infants you're looking at here are previously healthy children with no underlying immunodeficiency. Of those infants, 90 percent had received powdered infant formula.

MR. RATHKE: Take the slide off, please.
Q. Have you completed your conclusions? Did you reach any other conclusions?
A. In this part of the study, no. Well, my conclusions were that, in fact -- and, in fact, the lead to the Pediatrics article -- in Pediatrics they ask what this adds to the literature, and it was that full-term infants at home are at risk and the risk is to infants less than two months of age.
Q. Now, how -- in terms of methodology, would this have been a prospective study?
A. No, this was a retrospective.
Q. A retrospective. What -- explain quickly what the retrospective study is.
A. In a retrospective study you look back in time and collect information on cases that have already occurred to look at what is related to the development of disease in those cases.
Q. What is a prospective study?
A. In a prospective study, you select a population. You are interested in looking at a certain disease or disorder, and you follow that population through time until you either run out of money, everybody either gets the disease or dies, or you have for whatever reason a predetermined cutoff time. And at that point you're prospectively collecting data. At the end of that time point you look at your data. You see who's developed disease, who hasn't, and try to characterize and compare the

ones who have and haven't.
Q. One of Abbott's experts suggests that your retrospective study was an error and that the best way to study this is through a prospective study. What is your response to that criticism?
A. Oh, I absolutely disagree. If you tried to look at this rare disease prospectively, it would be prohibitively expensive. You would potentially not come up with a single case. There's a very high probability of that. And I'd be willing to bet a quarter you would end up with nothing because with rare diseases, prospective studies are pretty much the worst approach. Your likelihood of having enough data to analyze is extraordinarily low. And if it's an important disease, you've waited probably 20 years and come up with nothing.
Q. The same Abbott expert suggests that you should have done a cohort study. What is a cohort study?
A. A cohort study is where you do look at entire population. You would not be able to do a cohort study in this case because we didn't want to just -- I didn't want to just look at outbreaks. And if you include sporadic cases which are very important if you're looking at things occurring at home, they're not a cohort. So it would not be -- would not be a very feasible design.
Q. This is just a yes or no. Have various national or international agencies agreed with your conclusions, the

conclusions of your epidemiological study?
A. I don't know that they're agreeing with me so much as they have the same opinion, yes.
Q. All right. All right. Exhibit 148. Dr. Jason, you've referred a number of times to an FDA letter to health professionals. And bringing up Exhibit 148, is that the letter that you're referring to?
A. That is the revised version. They --
Q. That's the letter.
A. Yes.
Q. That's the letter that went out from the FDA to health professionals.
A. Yes.
Q. And that letter states on page 1 that clusters of E. sak -- that's in the very first letter -- very first paragraph of the letter. Do you see -- no, not that. Of the letter. Dear Healthcare Professionals, in that paragraph, the middle paragraph there. Could you bring that out? Clusters of ES infections in neonates have been reported in a variety of locations over the past several years among infants fed milk-based powdered infant formula from various manufacturers. Do you see where it says that?
A. Yes.
Q. Do you agree with that?
A. At the time, yes.

Q. Then -- when you say at the time . . .
A. Well, I think in fairness to the formula companies, this is 2002, so you just have to qualify that that's when this survey was done.
Q. Right. Okay. And then on page 2 of Exhibit 148, the health professionals level -- letter, it says that although the reservoir of the organism -- I'm not finding it real fast, so let's move on to page -- also on page 2, in light of the epidemiological -- on page 2 the paragraph that starts with the FDA, further down, okay, do you see where in that paragraph it says in light of the epidemiological findings and the fact that powdered infant formula are not commercially sterile products, FDA recommends that powdered infant formulas not be used in prenatal intensive care settings unless there is no alternative available? Do you see where it says that?
A. Neonatal, yes.
Q. And that's the summary or the key advice that was provided in that particular letter?
A. It was one key piece of advice. The other part was if you have to use it, the letter goes on to try and define ways that you could try to decrease the risk.
THE COURT: Mr. Rathke, I think you misspoke. You said prenatal, and the word in the letter is neonatal.
MR. RATHKE: Neonatal, I'm sorry.
Q. Could you turn -- let's go to Exhibit 84. Exhibit 84 is an

e-mail to a number of individuals including a person, Karl Erickson (sic), of Abbott. Do you see where it says that? Or he's a person that gets a copy of the e-mail I should say.
A. I believe -- I'm having trouble. Gotcha. Okay. Yes.
Q. And then the text of the e-mail says as reported on our conference call, attached is the risk profile of enterobacter sakazakii in powdered infant formula. Do you see where it says that?
A. Yes.
Q. And it goes on to say that this was prepared by the U.S. and Canadian delegations of CODEX. Do you see where it says that?
A. Yes.
Q. Tell the jury what CODEX is.
A. CODEX is an envir -- an advisory group that is organized by the U.S., and it advises the United Nations and WHO.
MR. RATHKE: And then if you'll go to page 2 of the document, Pat. Start at the top.
Q. There's some Latin there. Could you tell us what that says?
A. That's the name of the organization. The CODEX is just an abbreviation of the name of the group.
Q. All right. And then scrolling down under background, just highlight that first sentence. Do you see where it says enterobacter sakazakii has been associated with a variety of

severe and life-threatening conditions including meningitis, bacteria -- pronounce that for us.

A. Bacteremia.

Q. Bacteremia, what's that?

A. That is when the infection is spreading through the bloodstream to different parts of the body.

Q. And then what's the next term that's used there?

A. Necrotizing enterocolitis.

Q. And what's that?

A. That is a fairly complicated disorder of the intestines. Interestingly, I didn't show the results, but in that earlier time period, a relatively high proportion of infants had that. You don't see that any longer. And necrotizing enterocolitis is a problem that very young premature infants have. So again, what it reflects is a shift toward term infants that are no longer in NICUs.

Q. And then if you turn to page 2 -- or page 3 of the exhibit, do you see where it says E. sakazakii is known to be present in a portion of powdered infant formula and that such formula has been epidemiologically linked with illness in neonates and the disease may be life threatening? That's in the top paragraph there, not that paragraph, of the next one. Okay. Shout that out. Do you see where it says that?

A. Yes.

Q. And do you agree with that?

A. Yes.
Q. And is that consistent with your study?
A. Yes.
Q. And then in the next paragraph, CODEX states that powdered infant formula is the food item that has been linked with E. sakazakii infections. And then it cites some studies. And then it states there have been a number of outbreaks of neonatal E. sakazakii infection attributed to powdered infant formula in which identical organisms were isolated from ill neonates and previously unopened containers of formula. Do you see that?
A. Yes.
Q. And do you agree with that?
A. Yes, there have been a number of very elegant outbreaks that have done that.
Q. And then go to the next page, page 4 of the document, the third paragraph, please. Do you see where it says, beginning in that third paragraph, while the reservoir of E. sakazakii in many cases is unknown, a growing number of reports have suggested a role for powdered milk infant formula as a vehicle of infection? Do you see where it says that?
A. Yes.
Q. And do you agree with that?
A. Yes.
Q. Then finally to page 7 of the document, the paragraph entitled conclusions. Page 7. You're on 5. Now you're on 3.

Want to go to page 7. Paragraph under conclusions. Under conclusions CODEX says E. sakazakii is an emerging infection. Let's just start with that. What's meant by an emerging infection?

A. That we had not been aware of it in the past.

Q. It goes on to say that has been clearly linked with the conception of contaminated powdered infant formula. Do you see where it says that?

A. Yes.

Q. Do you agree with that?

A. Yes.

Q. Then further on in the paragraph it says at the very last sentence, powdered infant formula is not a sterile product and risk management strategies have to be developed in order to -- in order address the presence of E. sakazakii in this product. Appears to be a misprint in the text. But do you see where it says that?

A. Yes.

Q. And do you agree with that?

A. Yes.

Q. What is the American Academy of Pediatrics?

A. It's the association of pediatricians.

Q. And did they speak out with respect to E. sak and powdered infant formula?

A. They did as far back as 2003.

Q. Slide 32. Using the slide, could you tell us what the American Academy of Pediatrics stated.
A. They pointed out that the risk to term infants is not zero and that they did not accept that any level of risk should be allowed. The issue under discussion was how much risk can we tolerate. And so the AAP stand was we shouldn't be talking about accepting levels of risk.
Q. And that's August 28, 2003?
A. Correct.
Q. And who did they send that message to?
A. This was -- this was -- there was a lot of activity going on with the FDA in terms of what needed to be done. The meeting I mentioned yesterday, the 2003 meeting, was a part of that. So there was a lot of information being sent to CDC by various authorities saying what their stand was, and this was one of them.
Q. Was that the CDC or the FDA?
A. That was to the FDA.
Q. Right. Exhibit 96, please. Bring that up a little bit better. I thought we had the book. That's really hard to see, so I'm going to hand you Exhibit -- the real book.
A. Oh, sorry.
Q. Exhibit 96, and could you just hold that up for the jury to see?
A. (Witness complied.)

Q. And what's the title?
A. Enterobacter Sakazakii and Other Microorganisms in Powdered Infant Formula.
Q. And part of the title says meeting report. What kind of meeting are we talking about?
A. The World Health Organization or WHO convened a series of meetings about this problem, and the first one was in 2004, and this is the report of that meeting.
Q. And did -- in 2004 did you have a chance to review that or review it since?
A. Haven't reviewed it recently, but yes, I've reviewed it.
Q. Okay. Could you turn to page little Roman numeral 15. May be easier to do it here.

I'm showing you a page that's entitled executive summary. Do you see that?
A. Yes.
Q. And I'd like you to note the second paragraph which states after reviewing available scientific information, the expert committee concluded that intrinsic contamination of powdered infant formula with E. sak and salmonella has been a cause of infection and illness in infants including severe disease, et cetera. Do you see where it says that?
A. Yes.
Q. Is that a -- do you agree with that statement?
A. Yes.

THE COURT: Mr. Rathke, I think you took the auto focus off so when you enlarge it it's not focused but . . .

MR. RATHKE: Okay.

Q. The report also states in the executive summary that powdered infant formula is a food item that has been linked with ES -- or excuse me. I'm sorry. There's a paragraph that starts out E. sak -- E. sakazakii has caused disease in all age groups. Do you see where it says that?

A. Yes.

Q. It says from the age distribution of reported cases, it is deduced that infants, children of less than a year, are at particular risk. Among infants, those at greatest risk for E. sakazakii infections are neonates, under 28 days, particularly preterm infants, low-birth-weight infants, or immunocompromised infants. Do you see where it says that?

A. Yes.

Q. Do you agree with that?

A. I do with the caveat that they're not the only ones at risk.

Q. Now, the WHO also met -- the World Health Organization also met in 2006 and issued another report; is that correct?

A. Correct.

Q. And did they change any of the recommendations or conclusions that they had reached in the 2004 report?

A. Oh, I think they shifted emphasis, but the core issues

didn't change.

MR. RATHKE: Could you pull up Exhibit 111. And go to page 6 of the exhibit. Take that off.

Q. Do you know what a category A microorganism is?

A. In terms of these WHO categories, a category A microorganism is one where there is solid scientific evidence that in this case it is -- well, in this particular case it's that there's very strong scientific evidence that it is in powdered infant formula and causes disease.

MR. RATHKE: Would you go to page 26. Focus on the table.

Q. Showing you table 1. Explain what they mean by categories A, B, and C.

A. This is another way of saying that category A means that there's solid evidence, so you have clear evidence of causality. There's good scientific evidence that these organisms are in powdered formula and cause illness if an infant comes in contact with them.

Category B organisms are plausible but there's not been a scientific link, so, if you will, there have been good epidemiologic studies linking C. sak to infection in infants and to powdered formula. The organisms that are in category B, they're concerned. They know it can be in formula; they know it can cause disease, but you don't have that incredibly solid evidence.

Q. And to be clear, the title of table 1, would you read that to us?
A. Categorization of the microorganisms or microbial toxins of concern in powdered infant formula based on the strength of evidence of a causal association between their presence in PIF and illness in infants.
Q. Thank you. You can take that off. Are you familiar with or did the -- did WHO put out another report on this subject in 2008 concentrating on follow-up formula?
A. Yes.
Q. Did they change any of the recommendations that had been made in 2004 and 2006?
A. Again, not really. I think emphasis again shifted, but the core things didn't.
Q. Let's take up Exhibit -- Abbott Exhibit 1019. Are you familiar with that document?
A. It looks familiar, yes.
Q. Could you tell the jury what it is.
A. It is -- it's a -- looks like a CODEX document, and it's offering advice about -- advice related to powdered formulas and their use in young infants and children.
Q. Could you -- and do you see where the date of that exhibit is indicated at the top?
A. 2008, yes.
Q. Would you turn to page 2. And towards the bottom,

paragraph starting while PF, towards the bottom. Yeah, shout that out. PF is the apparent abbreviation for powdered formula. Do you see where it says while powdered formula was established as the source of E. sakazakii, paren, cronobacter species, close paren, in some of the cases, in many others it was neither epidemiological or microbiologically implicated as the source of the infection. However, in such cases, no other source of infection has been epidemiological or microbiologically implicated. Do you see where it says that?

A. Yes.

Q. Is that a true statement?

A. I think it's a confusing statement that probably was a compromise among trying to get everyone to agree.

Q. Well, how about that second sentence?

A. I certainly --

Q. That no other source of infection?

A. That I certainly agree with. There has never been any shown -- no association has ever been shown scientifically between C. sakazakii infection in infants. There's never been association found between anything but PIF and that disorder.

MR. RATHKE: I'd like to bring up Exhibit 147 but not on the screen. Exhibit 147 is a document before the Court, and the plaintiff would move for admission of Exhibit 147. There have been objections under category B.

THE COURT: Is it a relevancy objection?

MS. GHEZZI: Your Honor, I can't see the exhibit on the screen.

THE COURT: Well, we can't hear a word you're saying, so you're not making any record.

MS. GHEZZI: I apologize.

THE COURT: So either don't say anything or speak into the microphone.

MS. GHEZZI: Okay, Your Honor. I can't -- he put it up. I couldn't see it. Excuse me.

Your Honor, the objection was that it was hearsay and because of the date it wasn't relevant.

THE COURT: That wasn't your objection to 147. That wasn't your objection.

MS. GHEZZI: That's the objection right now.

THE COURT: Well, it's too late.

MS. GHEZZI: Well, okay.

THE COURT: Do you even know what your objection was in the pretrial order?

MS. GHEZZI: Your Honor, without looking at it right now, I can't remember what all of the objections are.

THE COURT: Yeah, because you make so many of them, it's hard to keep track of them, isn't it? Isn't it? You think you'd know what objection you have to it.

MS. GHEZZI: Your Honor, I know what it is. I didn't know he was going to put 147 up right now, so I haven't pulled

it out, but I can get it.

THE COURT: You don't know what it is.

MS. GHEZZI: I don't know without looking at it.

THE COURT: Okay. Well, the objection's overruled.

MS. GHEZZI: Okay. Thank you, Your Honor.

THE COURT: Thank you.

BY MR. RATHKE:

Q. Okay. Do you see Exhibit 147? Could you identify what that is?

A. That is a website, the CDC website, their page on cronobacter infection.

Q. Who issued that?

A. Centers for Disease Control. It's from the CDC website.

Q. And what is the date of the -- approximate date of the document, not nec -- in the lower right-hand corner is -- that's just the date it was printed I believe. But do you know when this document was issued?

A. If you go to the very last page, what it should say at the bottom is when it was first put up and when it was last updated. The web pages theoretically if people can keep up with them get updated periodically so people who go know whether, you know, this is outdated information or whether it's still current.

Q. Okay. Page 4, it says this document was issued on April 11, 2002, and revised on October 10, 2002, so . . .

I'm sorry. Go back to the first page, please.

Highlight where it says rare but serious illness in infants.

Now, you'll see in that paragraph that he's called out that there's reference to CDC being informed of the total of 13 cases in 2011. Do you see where it says that?

A. Yes.

Q. The sentence -- that paragraph begins with the statement that cronobacter illness is very rare but is often deadly in young infants. It usually occurs in the first days or weeks of life. Do you see where it says that?

A. Yes.

Q. Now, where it says 13 cases, going back to your study which I know had been completed by then, is that consistent with other years, or was that a spike?

A. When you're talking about case numbers this small, I don't know that you can really differentiate. In general there are about five cases a year. What we don't know here is I'm talking about invasive cases. And I don't have enough information on these 13 to know how many of them are invasive and how many are not as severe. But it's certainly -- it's a large number of cases if it's all invasive.

Q. In the next paragraph by the picture it states that in infants the illness generally starts with fever. Do you see where it says that?

A. Yes.

Q. Is that -- is that accurate?

A. Yes.
Q. It includes poor feeding, crying, or listlessness. Is that accurate?
A. Yes.
Q. Then the next page where it says powdered infant formula is not sterile, could you highlight that? That paragraph states that manufacturers report that using current methods it is not possible to eliminate all germs from powdered infant formula in the factory. Do you see where it says that?
A. Yes.
Q. And then the last paragraph in that sentence, very -- or in that paragraph, same paragraph, very -- very young infants, infants born prematurely, and infants with weakened immune systems are at the highest risk. Do you agree with that?
A. Yes.
Q. Now, the document makes reference to those 2011 cases you'll recall.
A. Yes.
Q. Was there any analysis by anyone of the strain types of the C. sak that was involved in those 2011 cases?
A. Yes.
Q. Would you tell us about that.
A. Could I have slide 57?
Q. Now, you got a date there, 2012.
A. That's when they did this work. That's when they

published -- that's when they pub -- well, they did posters on this work.

Q. But that refers to the 2011 cases?

A. Yes.

Q. All right. And what -- what did the studies show about those cases?

A. Okay. If you recall yesterday when everybody was incredibly tired, I talked about a laboratory that was looking at something called strain type. And what they had found was actually two labs working together looked at all their stored cronobacters and then after they -- and they put them into groups based on a genetic sequence. And then they looked at the characteristics. And what they found was that there were a lot of different strain types but only one caused invasive infection. It happened only in infants, and it also happened to be found only in powdered infant formulas.

Now, their samples were from at least a 20- or 30-year period and were from 7 countries. And so their bottom line was that this seems to be a very stable strain of C. sakazakii. Remember there are a lot of different strains of C. sakazakii and that it clearly caused, for whatever reason, severe meningitis in infants.

Well, the FDA looked at samples from the 2011 cases and worked with these labs and developed -- there are very few labs that do this technique, the two labs that first published.

Now the FDA and CDC is working with one of the original labs. And so the FDA developed the technique, and this is the information they got from those 2011 cases which were distinct from one another. They were at-home cases. They had no relationship to each other. They had no relationship to all those earlier isolates. And what they found again was that they were all ST4. All of the environmental isolates in the household investigations were ST4. And for six cases, they did find C. sakazakii in the PIF that the infant had had, and all of those were ST4. And it matched the -- and they matched the infant's isolates.

Q. When you say matched the infant's isolate, what are you --

A. That's a good question actually because -- because I want to be fair about that. Realize technology has moved forward, so what was a match in the past was based on technology at that point in time. A current match now means I actually go ahead and do what's called polymerase chain reaction, and they look at genetic sequences, so they can do very tight matching. Now, I'm sure ten years from now we won't be happy with that, but that's what that means.

Q. What does that mean with respect to the 2012 study when it says they matched the clinical isolate? Just tell us what that means.

A. It means that the infected infants and their powdered formula had exactly the same bug which means that's where it

came from. And the environmental testing that was positive almost certainly was due to contamination from the powdered formula, not the formula -- not the environment to the formula.

Next pa -- next slide.

What they found was that their isolates -- again, we're talking about families. They grouped into three families. And we already talked about the fact that there was a relationship between the clinical and the powdered formula samples. And the FDA pointed out that these clusters were from kids who had no relationship to each other. They weren't having the same lot of formula, and yet it was clearly the same bug.

So their conclusion is they've got contamination that is long and ongoing and by inference it's at the factories. It's not something that -- you know, it's not going to be in one home in one state and one home in another state.

Q. Do the next one, 59. Go ahead with --

A. And basically the only thing that these infants had in common is they all had PIF. They did not have the same lot of PIF. And again, they were all in the ST4 family.

Q. Now I want to go to another subject which is --

A. Oh.

Q. No, we're going to go --

A. Okay.

Q. I'd like to talk about Jeanine's infection. You looked at this case; correct?

A. Correct.
Q. What are -- what sources of information did you have regarding this case? What'd you look at?
A. I looked at medical records. I looked at CDC records, FDA records. I looked -- I looked at depositions. I looked at Abbott records in terms of the lot.
Q. Did you review the deposition of Jeanine's mother, Megan Surber?
A. I did, yes.
THE COURT: You know, we went through all this yesterday.
MR. RATHKE: Yes.
THE COURT: It's exactly what you asked yesterday.
MR. RATHKE: I'm sorry.
BY MR. RATHKE:
Q. What are the -- what circumstances did you determine occurred in Jeanine's case? And let's start with her birth.
A. You mean describe her birth?
Q. What your -- what your underlying assumptions are with respect to her pregnancy and birth.
A. Okay. Well, Mrs. Surber had a pretty uneventful pregnancy. She was healthy. She smoked, was trying very hard to stop smoking and decreased it, but that didn't have a impact. She really had a very good prenatal course. She had had an elective C-section with her first child and so decided to go ahead -- her

obstetrician decided they would have an elective C-section with this birth. She was carrying twins, and so on April 14 of 2008, they went ahead and did an elective C-section. Jeanine was born first. She was 200 -- 2,220 grams which is slightly low birth weight.

Q. What does that compute to to pounds and ounces?

A. About something like 5 pounds, 14 ounces, something like that, not -- she's not a bad-sized baby, but she's slightly a little small.

Q. If the records indicate it was 4 pounds, 14 ounces --

A. That would fit. She weighed more than my preemie. I remember it.

Q. How about her hospital stay?

A. Her hospital stay was very uneventful. They fed her ready-to-feed formula. That was the only thing she got. She grew, fed well, and on the third day of life came home.

Q. Is that the norm for a cesarean?

A. Yes, yeah, harder on the mother than baby.

Q. What's your understanding as to what Jeanine was fed when she got home?

A. It's my understanding that the mother continued with ready-to-feed formula until she ran out of it. On April 23, she began powdered infant formula, Abbott's NeoSure 22.

Q. Do you recall what time of the evening it was or what time of the day it was on April 23?

A. Approximately 9 p.m.
Q. And were there additional feedings during the course of that evening and the following morning?
A. Through the night there were. Jeanine had a feeding at around midnight and a feeding at 4 a.m. that she apparently took well and on schedule. And then in the morning --
Q. Let me stop you there.
A. Uh-huh.
Q. What is your understanding as to how -- you know, how that night progressed from 9 p.m. until 4 a.m.?
A. My understanding was that everything was very normal, that Jeanine slept in a crib right by her mom's bed so that her mom could hear her cry when it was time to wake up for feeding and that the midnight and 4 a.m. feeding, everything was very much the way it normally was. In fact, the mother commented -- I think she was asked in her depo about taking her temperature, and her response was no. At that point there was no reason. She was acting fine, that she didn't feel warm. So . . .
Q. After the 4 a.m. feeding, what was your -- was it your understanding that Jeanine fell back to sleep again?
A. That was my understanding, yes.
Q. All right. And then do you have an understanding as to when about she woke up?
A. Yeah. The impression I get, that it was probably around 6:30 or thereabouts that she started waking up and being cranky.

Q. What did the mom do in response to her being cranky?
A. At some point early that morning -- I don't know if it was before or after the 8:30 a.m. feeding -- she did take her temperature, and it was normal. And so she tried to feed her her 8:30 feeding. Jeanine didn't take it well, so she very appropriately threw that out, mixed up some new formula, and I think that's kind of how the morning went, that she was definitely cranky.
Q. As the day progressed, what is your understanding?
A. That she became increasingly cranky. I think the mother had -- April 24 was not a good day for this mother. James had been in the hospital, and she got called that it was time for him to come home.
Q. Why had James been in the hospital?
A. His father has hereditary spherocytosis.
Q. What's that?
A. It's a blood disorder where the red cells aren't shaped quite right. It's -- you have a range of effects. It wasn't really anything very major for the father, but they wanted to see if he had it as well. And he also wasn't feeding as well as Jeanine had been feeding. So she had to get him home, but Jeanine was getting crankier and crankier. The mother ran to get James, came back. Jeanine was even crankier. So I think that's how her day went.
Q. During the course of the afternoon, was the baby's

temperature taken again?
A. Yes. According to the mother, she became progressively worse. At one point she said --
Q. Who became?
A. Jeanine, that she was at one point I think she said crying like a hyena and the mother was getting very worried. She took the temperature again, and at some point that afternoon -- I think she may have taken it twice. She was unclear about it. But the first time that it was elevated was in the late afternoon. It was 100.7 which is a low-grade fever but for an infant is not good. So at that point she called her pediatrician.
Q. And what's your understanding of what the pediatrician advised?
A. They told her to come to the office, so she got in the car, got to the office, and didn't see the pediatrician. At that point they told her to go to the emergency room.
Q. And that would be at St. Luke's?
A. Correct.
Q. Was that appropriate that she be taken to the emergency room?
A. Yes.
Q. And what -- what's your understanding as to the eventual diagnosis for Jeanine?
A. They did a work -- a septic work-up which is a blood

culture, and that was all appropriate. They did a spinal tap, and she on the basis of that clearly had meningitis. They started her on antibiotics, and the next day the cultures from the spinal tap grew out enterobacter sakazakii.

Q. Is it important in a case of bacterial infection to identify the bacteria?

A. It is certainly ideal. For instance, this organism is not -- many -- many E. saks are not sensitive to what you normally give a child if you're just trying to cover for any possible cause of meningitis.

Q. I believe your testimony is first they determined it was meningitis and then gave her medication before they identified the organism; is that correct?

A. Correct.

Q. And is that an appropriate way to treat meningitis before you've identified the bacteria?

A. Once you've got that spinal fluid, you start treating.

Q. And then once they made an identification, did they continue with the same medication, or as a result of the identification, did they shift to another type?

A. They shifted.

Q. Was the diagnosis, treatment, and care that Jeanine received at St. Luke's Hospital appropriate?

A. Yes.

Q. How long is it your understanding that she stayed at

St. Luke's?
A. Well, she was transferred fairly soon because of her condition. She was hospitalized for quite a long time period.
Q. And that would be where?
A. At -- in Omaha at the Children's Hospital.
Q. And did you review those medical records of the Children's Hospital hospitalization?
A. Yes. Well, the acute phase of it, yes.
Q. And was the care and treatment at Children's appropriate?
A. Yes.
Q. Okay. I'd like to go to another subject which is would you define infectious dose for us and in particularly how it relates to Jeanine's case.
A. I think we talked about this a bit yesterday. The infectious dose is a -- it's a somewhat abstract term. It is an abstract term. It's the amount of a bacteria -- of a virulent bacteria it takes to cause an infection.
Q. And will that vary from bacteria and type of bacteria to another?
A. Yes.
Q. How is that?
A. Well, the more virulent bacteria will likely move more quickly. Just by the nature of different bacteria, they'll have different incubation periods. So enteric bacteria will potentially move more quickly than a parasite would. Different

strains even within a given group of bacteria will move more rapidly. We know that just by the nature of her course that Jeanine had a very virulent bacteria. And so you would expect that its infectious dose is probably pretty small.

Q. Could Jeanine have received an infectious dose in one feeding of powdered infant formula?

A. Yes. If you -- I didn't present all these studies, but the studies show with a virulent C. sakazakii as little as a thousand cells can progress. One study -- well, I guess I shouldn't say anything further.

Q. Well, tell us about -- is there a particular study that proves the point, or is --

A. Well, I guess yeah. There are two studies. One basically is like the other. That one group took a single colony forming unit and put it into a little bit over three ounces of reconstituted formula, and they let it grow at room temperature, and ten hours later they had ten million cells.

Another lab did the same sort of thing with an isolate they had from one of the outbreaks that were investigated back in 2002. And they had that same massive growth rate in a very short period of time. And probably the most striking part was it was at room temperature. It wasn't even at the optimal temperature for this bacteria to grow.

Q. Elaborate a little bit more on the media that was used in those studies and the media that would be present or the

environment that would be present in Jeanine's intestines.
A. Okay. Well, clearly it was not as optimal as her intestines would be. And it's for the reasons that we talked about when I was talking about the development of the intestines. There are a lot of very good nutrients in those intestines. It's very warm. It's an ideal environment for growth.
Q. Now, one of Abbott's experts reached the conclusion that she did not consume enough powdered infant formula to receive an infectious dose. And you read his report.
A. Yes.
Q. And you also read the deposition I took of him.
A. Yes.
Q. Is he wrong? And if so, why?
A. He was wrong. He seemed -- number one, he based -- he based his opinion on two assumptions. He looked at actually the information you showed from the FDA survey and used that as a basis of how much contamination there is in powdered infant formula.
Q. When you say the FDA survey, you're referring to the 2002 survey that the FDA did of all of the companies?
A. Correct.
Q. And they found that a certain percentage of cans had E. sak and they determined the average amount of E. sak of those -- of that population?

A. Correct.
Q. And how did he use that as an assumption in his opinion?
A. Well, that assumption honestly is probably not quite fair to the manufacturers because I think powdered formula is cleaner now than it was then.

But he also assumed that it was evenly distributed throughout the entire lot. And remember there's very little that's consumed. So when you do that, basically you say, well, she got maybe one cell maximum. Well, we know that's not how C. sak contaminates powdered formula. It's in clumps. So you can't take an average when something is not homogenously distributed. The concept is just simply incorrect statistically. If there's a clump here and nothing else everywhere else, what you want to know is how much is in that clump, not if I spread that clump out through the entire lot how much would I have. So I disagree. What he did made no sense at all.
Q. And anything else about his report that you feel is erroneous on that subject? I just want to make sure you've covered everything.
A. On that particular topic, I think that -- well, he talked later about incubation.
Q. Right. We'll get to that.
A. No, nothing more about that.
Q. Now -- and let's take us to incubation time. What are

the -- what is incubation time?
A. Incubation period is usually how it's referred to, and it's a time between when -- again, I think we talked about this a bit yesterday. It's the time between when a virulent bacteria or organism enters the body and when the person shows the first signs of infection.
Q. And what are the factors that determine the incubation period?
THE COURT: Yeah. Why don't -- before we get to the factors, why don't we take our mid-morning recess. Members of the jury, it's ten o'clock. We'll be in recess until 10:25. Please remember to keep an open mind until you've heard all the evidence. Thank you.
(The jury exited the courtroom.)
THE COURT: Anything we need to take up?
MR. RATHKE: No, Your Honor.
(Recess at 10:02 a.m.)
THE COURT: You know, I made a huge mistake not putting you all on the clock because there's no way you're going to be done with your case by Friday at this pace. It's just not physically humanly possible, so not very happy about it.
Have the jury brought in.
(The jury entered the courtroom.)
THE COURT: Thank you. Please be seated.
Mr. Rathke, you may continue.

BY MR. RATHKE:
Q. In the history of Jeanine when you -- when she was in the hospital at her birth admission, was she in NICU?
A. No.
Q. So she was just where routine new babies are born.
A. Well baby nursery, yes.
Q. Well baby?
A. They usually call that a well baby nursery, yes.
Q. All right. And you indicated that an infectious dose would be about a thousand cells or less. How big is that?
A. You wouldn't be able to see it, you know, without a microscope.
Q. Is there any clinical basis for your opinion about -- relating to the thousand cells?
A. Actually there is. In 2010, two infants in Mexico who were hospitalized were given a U.S.-manufactured product. I have no idea whose. I did not want to know. But the people caring for the patients did write it up, and I talked to them. It was unique because they did isolate it from the powdered formula and from the infants. The infants got necrotizing enterocolitis and very bloody diarrhea, and they were able to calculate how much of a dose they got before they became symptomatic, and it was indeed in the range of one or two thousand cells.
Q. Now let's go to incubation period. What are the factors that determine incubation period?

A. Incubation period, there are probably at least four factors involved in that. One would be lag time.
Q. What's lag time?
A. Lag time is the time it takes for a cell to go from being resting to get revved up and start dividing.
Q. Then next?
A. Then would be the growth rate, and that is how quickly a cell goes from being one cell to two cells, then two cells to four cells, four cells to eight cells. So it's the replication time.
Q. And does the baby's body and the intestine have anything to do with the growth rate?
A. Well, absolutely. I think there are a number of factors that affect growth rate, and two of the things that do affect it are things we've talked about: The nutrient conditions. If you have very rich nutrients, the growth rate will be faster. If the temperature is at the optimal range for that bacteria, you'll have your faster replication. So a newborn infant when it's an aggressive invasive C. sakazakii would be optimal for very rapid growth rate.
Q. How about -- is nutrients a factor?
A. Very -- yes, it's a major factor.
Q. Do you have an opinion whether the interval between Jeanine's first powdered infant formula feeding and the onset of her symptoms was within the incubation period that you'd expect?

A. I do.
Q. And what is that?
A. I think it is within the potential incubation period for some strains of virulent C. sakazakii.
Q. Now, Dr. Shulman states that the incubation period is much longer, and you read his report and deposition where he stated that; correct?
A. Yes.
Q. Why is he wrong?
A. Well, I think he misinterprets the Mittal study that I told you about where they --
Q. That's the one with the rats?
A. The mice, yes.
Q. The mice?
A. He ignores the fact that they were floridly symptomatic by 12 hours. He also uses a -- actually he uses a cyclical false logic that -- that defense lawyers have accused me of. He says that you couldn't possibly have an infection in less than three days, and so he says that any case that happens less than three days after first receipt of powdered formula by definition isn't from the powdered formula; and, therefore, the incubation period is longer than three days.

In reading it it reminded me -- I was very involved in the early days of AIDS surveillance, and what we found was that doctors were not reporting women who had clear symptom of AIDS,

and when we would ask why they didn't report it, they said, well, that was because only gay men get AIDS. It's this -- basically you redefine it by your own terms. If you don't report it and acknowledge it, it never happened. So I think that's the kind of logic he's using.

Q. Both Dr. Polin and Dr. Shulman point to Jeanine's crying during the evening of April 23 as proof that she had an E. sak infection before she even consumed the powdered infant formula and, therefore, ruling it out. Are they correct? And you read that.

A. I did, yes.

Q. Okay. Are they correct?

A. It's my opinion that that was not the case.

Q. Have there been some studies on infant crying behavior?

A. There have been probably 60 years of studies on crying behavior.

Q. That'd be slide 40. Using slide 40 and later 41, could you explain why they're wrong?

A. They are exactly right that a seriously ill infant or what we call a septic infant, an infant with bacteria in their bloodstream, they will cry sooner or later. They will be irritable. They will cry. But very, very few infants that cry are septic or severely ill. Crying is just very, very common in an infant, and I think any of us who have babies know crying is very common and that's why it's hard to be a pediatrician

because you have to know what other things are going on to differentiate a healthy crying infant from one who's very sick.

This is a quote from Dr. Polin, and it basically says, you know, it's very hard when you've got a child who's sick -- rather, crying to know what's going on.

I guess the next slide.

Okay. This is a really old study from 1954, and it shows what all of us parents know which is babies cry, and they tend to cry at night right around the time that Jeanine's mother noticed she was crying, namely the magic hours of eight to ten when you want to go to sleep and they just won't let you go to sleep.

So crying is very, very common. 99 percent of infants that are crying are not seriously ill. So as a pediatrician, what you have to look for are what are the other signs that an infection is going on and this is just not normal crying behavior. And what you look for first and foremost --

Q. Let me ask you this. What are the -- what are the signs in Jeanine's case that would point to whether or not she had an infection when she was crying that evening?

A. The evidence I see that says that crying was not related to her illness is that she went to bed normally following her nine o'clock feeding. She woke her mom up for her routine midnight feeding. She went back to sleep -- and she took it well. She took her midnight feeding really well, took her 9 p.m. feeding

really well, slept between her feedings, took her 4 a.m. feeding very well and slept normally.

She was a -- she had no fever when her mom checked her the first time. You would not have that happen in a child with a severe infection. So you don't just look at crying. You look at all these other things. And per the CDC website, fever is a major factor as well as inconsolable irritability which is what the mother described in the morning. So you would not have had an entire normal night of sleep if she had actually been septic early on. She wouldn't have gotten better and then worse again.

Q. Earlier yesterday you -- in giving -- in summarizing the points that you thought were important in reaching your opinion, you mentioned the conditions in Abbott's plant. With respect to that conclusion, do you have any expertise in the manufacturing field?

A. No.

Q. And what information did you use to reference that particular factor?

A. Dr. Scott Donnelly's report concerning the Abbott factory information we all received.

Q. Okay. Then on the question of -- would you consider yourself an expert in microbiology?

A. I do know microbiology but not as well as some of the other experts, no.

Q. And you've been making reference to Catherine Donnelly?

A. Correct, and Dr. Farmer.
Q. Let me go to another subject which would be the alternative possible sources that Abbott is suggesting. Can E. sak get into an infant any other way other than the mouth?
A. It would be extraordinarily unlikely. Enteric bacteria are not spread by aerosol. You do not get them by coughing. It is hard to get an enteric organism into the lung even if you're in a lab and you shove it into the lung.
Q. Can we rule out ready-to-feed as a source of Jeanine's infection?
A. Ready-to-feed is sterile when it leaves the factory. And if not, the manufacturer has bigger problems than PIF and E. sak. So I would hope you could rule that out.
Q. How about city treated water? Could we rule that out?
A. Yeah. There has never been a case of U.S.-treated municipal water that had cronobacter in it. But even if it did, Jeanine's mother boiled the water. That will sterilize it. It will kill any bacteria, not just cronobacter, any bacteria in that water.
Q. Abbott points to other persons -- persons that the infant had contact with before she developed the infection. Did you see any contact with any persons that would be unusual or out of the norm for a family that has just made a new addition?
A. No.
Q. Slide 46.

MR. PERSONS: I'm sorry?

MR. RATHKE: 46, slide 46.

Q. Using the slide as a summary, could you go through the factors that cause you to eliminate other people as a source of Jeanine's infection?

A. Yes. Again, we talked about this. Cronobacter, never mind ST4 cronobacter, does not live in the human body. It has been found in people other than infants, but these are people that are sitting in hospitals, not visiting new babies in their homes. And it does not colonize let alone infect normal, everyday, average-age people. By her mother's history and her grandmother's history, Jeanine had contact with very few people. These were not people that were wheeled in out of a hospital.

Her twin brother shared many things with Jeanine. He shared the same womb. He shared the same birth. He shared the same birthing hospital. He shared the same home when he came home. The one thing he did not share with her was he never received powdered infant formula. It's my understanding that he is completely normal. And remember if you're terrified of spreading this around, all newborn infants have contact with lots of people, and they are not all coming down with cronobacter.

Q. The defense particularly points to Jeanine's father, Troy Kunkel, and that he had pneumonia. Could you discuss the possibility that he could have been a source of the infection?

MR. RATHKE: And put up slide 49.

A. Troy Kunkel was a young man. He did have one -- well, he had a couple of chronic health problems. He did have the spherocytosis which was not causing him any great problems and certainly wasn't making him immunocompromised. Like many people, he also had diabetes mellitus, and he was diagnosed with that shortly before Jeanine became ill. And at the time he was diagnosed, he came to the hospital with what you classically see in a newly diagnosed, moderately severe diabetic. He was not to my understanding an obese man. It really was his pancreas had given out. And so he had very high blood glucose levels which tends to make you what we call ketotic. You get nauseated. You do not get diarrhea.

And so the symptoms he had were not the symptoms you would get if you were one of these elderly hospitalized people in an ICU with cronobacter. Again, it is an intestinal organism. He had no signs of anything going on in his intestines. And as I say, cronobacter is not associated with diabetes.

Next slide.

On April 25, the day after Jeanine was hospitalized, he went to the hospital with a lot of complaints and clearly was very anxious. They felt that he had viral-like symptoms. When he told his physicians that his daughter had just been admitted with meningitis, they became concerned that maybe there was

something going on and that he had caught something from her. And so they admitted him for observation for a day. They clinically diagnosed him with having pneumonia. I don't believe they had chest X-ray confirmation. But their concern was that he had a viral pneumonia, and he left the next day.

Again, this is not a pulmonary organism. This is not how it presents. And there's no reason to think that anything that happened to him that day had anything to do with Jeanine's infection.

Q. Jeanine was living in the environment of her home. Did you see anything in the home environment as you understand it that would rule in or rule out that as a source of her infection?

A. I think we have a slide for that.

Q. Fifty-two?

A. Before Jeanine was born, the family went to a lot of effort to clean the house. Troy Kunkel, Jeanine's father, and Jeanine's older brother were in charge of the household cleaning. And so Jeanine's mother did not have to handle anything that theoretically could have been contaminated with cronobacter, but the house was kept very clean in preparation for her and James coming home.

The mother before she fed Jeanine boiled everything she used for mixing and boiled the bottles and the formula as well as the water.

Of these theoretical sites where cronobacter might

exist like toilets -- and I think they mentioned b -- they mentioned all sorts of things -- these are not things that Jeanine would have been fed. It would not have gotten down Jeanine's mouth. So these theoretical sites in terms of how Jeanine would ingest this organism don't make a whole lot of sense.

CDC did test the kitchen, the Kunkels' kitchen, after Jeanine became ill. Did they test absolutely everything in the kitchen? No. Is that ever done? Unfortunately, no. Was it done the very second she got infected? No. But they did come in. The health department did test, and they found no cronobacter of any sort.

And again, remember that James came home to the same environment, and he is a healthy child.

Q. In your answer you used the term reconstituted. Maybe you better define that term.

A. It makes just, you know, what -- the water you mix the powder with.

Q. How likely is it that Jeanine could have developed cronobacter -- a cronobacter infection from anything in her environment, you know, the place that she was living, the people that she was around?

A. I think it's very unlikely.

Q. Now I'd like to go to the label.

MR. RATHKE: Would you pull up -- I think it's 2027.

2027 I think is what we want.

Why don't you hold it there.

Q. 2027 is the joint exhibit that is the label of the can in question.

THE COURT: That's not -- that's 2013.

MR. RATHKE: I'm sorry. 2013 is.

THE COURT: You were talking about 2027.

MR. RATHKE: 2013, that's what that is. Now would you go to 2027 -- or 20 -- whatever is that blow-up. And see if you can enlarge it a little bit.

Q. What's on your screen are the directions for preparation. Let's look at the first few sentences. Says your baby's health depends on carefully following these easy directions. Is that an appropriate comment?

A. Yes.

Q. Proper hygiene, handling, and storage are important when preparing infant formula. Is that an appropriate comment?

MS. GHEZZI: Objection, Your Honor. Foundation.

THE COURT: Overruled.

Q. Is that a -- I read that second sentence. Is that an appropriate comment?

A. Yes.

Q. Okay. Failure to follow these directions could result in severe harm. Is that an appropriate comment?

A. Yes.

Q. Powdered infant formula is not sterile. Is that a true statement?
A. That's correct.
Q. Although Similac NeoSure is formulated for premature infants, powdered infant formula should be fed to premature infants or infants who might have immune problems as directed and supervised by your baby's doctor. Is that an appropriate comment?
A. I think that's an incredibly confusing comment.
Q. Why?
A. I think it's your classic mixed message. I -- especially in light of the fact that I think you need to realize until my paper pediatricians had not -- had been led to believe that an infant living at home was not at risk of this infection. So he'd have every reason to say sure, go ahead and use it.
Q. How about the next sentence, consult your baby's doctor about the formula appropriate for your baby, the need to use cooled, boiled water for making -- for mixing, and the need to boil utensils, bottles, and nipples in water before use? Is that an appropriate comment?
A. Well, it's always good to ask your doctor I guess.
MR. RATHKE: Go back to normal size, and then go to the directions for mixing which would be in the upper right hand.
MR. PERSONS: You want the little pictures?

MR. RATHKE: Sure.
Q. Those are some directions. Are those appropriate directions?
A. Yes.
Q. And from your understanding, did Megan follow those directions?
A. She did even better than these directions. She certainly did all of this and was even more careful.
Q. How so?
A. Well, you notice the last thing it said was ask your doctor if you need to boil your bottles and what not. Well, she boiled her bottles and what not. She was very good about throwing out whatever was not fed. She followed every single guideline of the American Academy of Pediatrics, FDA guidelines, dietetic association guidelines and was even more careful.
MR. RATHKE: Get rid of the -- head out and -- no, no, I don't mean get rid of the page.
THE COURT: What exhibit number is this?
MR. PERSONS: I have it as 28.
THE COURT: 28? Okay.
Q. Go up the next part where it's lighter colored. What size formula was Megan making for Jeanine?
A. That's another example that she was very careful. She -- for the initial feeding, Jeanine's initial feeding, she mixed the formula up right at the time of feeding, fed it quickly, and

discarded whatever wasn't fed. For her midnight and 4 a.m. feeding, she mixed those up before they went to bed which makes sense. You're tired. She mixed up only as much that Jeanine was going to eat at a feeding, put those into individual bottles that had been boiled, did all of the mixing, and so had two individual servings that she put in the refrigerator and then at the point of feeding warmed those up; again, fed Jeanine, got rid of the rest of it. So she, in fact, did even better than these recommendations.

Q. Okay.

MR. RATHKE: Get rid of the -- and then the very bottom, the last part of the panel.

Q. And were those instructions at the bottom of the panel followed?

A. As I say, the longest that she had a bottle stored would have been the one she mixed up before midnight that she fed at 4 a.m. So, in fact, she was much more careful than the recommended.

Q. If there is cronobacter in a can of powdered infant formula that's already there, would any of those instructions minimize the risk?

A. FDA and WHO's guidelines were on the assumption without evidence -- I mean a hope and a logical thought that it would decrease the possibility of the bacteria dividing to an infectious dose. If you look at the cases of infectious

invasive cronobacter, there were at least two hospital outbreaks where all those directions were followed and it still happened. And acknowledging that there's recall bias, parents may not remember everything perfectly, there were at least ten cases where all those directions had been followed and the infants still came down with invasive infection.

Q. And specifically -- I'm just asking you about the instructions, you know, washing your hands, possibly boiling tap water, boiling the bottles. Will any of those steps that are suggested or at least referred to in the panel of the label, will that do anything to kill bacteria that's already in the can?

A. No. What those do is it prevents what we call extrinsic contamination.

Q. What do you mean by extrinsic contamination?

A. Where you introduce the bacteria in the process of preparing the formula. But if it's already there, it won't have an impact.

Q. If it's already there, that would be called what as opposed --

A. It's called intrinsic contamination.

Q. Do you have an opinion based upon your education, training, work experience, your review of the literature, your review of the materials, and your review of the materials provided in this case regarding what information Abbott should reasonably provide

on its labels to consumers regarding the risk of bacterial infection?

A. I do.

Q. Okay. Go ahead and give those opinions.

A. It's my opinion that Abbott could do one of two things. They could change their label to point out that it does con -- that powdered formula does contain bacteria and that on rare occasion it can contain virulent bacteria that can cause severe infection in very young infants and ideally also educate parents on what it means to -- when you say something is sterile and the implication so that they can weigh the many real benefits of powdered formula against the risks.

Alternatively, they could say that this formula is only for infants greater than two months of age. It still would be nice to educate the parents, but I think doing one of those or both of those steps would be what parents deserve in terms of being fully informed in their decision making.

Q. Now, if a infant, if a newborn, is not breastfed, is there any safe alternative to feed the child other than formula?

A. Other than formula?

Q. Other than formula.

A. I don't think so, no.

Q. Okay. And is there -- is there a formula available to parents for newborns that avoids the risk of E. sak contamination?

A. Yes.
Q. And what is that?
A. Jeanine got it: Ready-to-feed formula.
Q. What about the argument that ready-to-feed is more bulky since you're carting around a container that's got the liquid in it too so it's not -- you can't put it in your purse or a bag? What about that argument?
A. I have been told the argument that it's too heavy and I -- you know, I'm not the strongest person on earth, but a very young infant doesn't drink that much formula. I know for a fact I can lift those containers, and I think other mothers would be willing to do that too. It's not like we're running around -- you're taking care of a newborn infant.
Q. How about the convenience that you can take ready-to-feed when you're out and about, you know, you can just take a can as opposed to a bottle?
A. I'm not sure -- if you're saying are there little containers of ready-to-feed, yes. A lot of mothers do that when they go places. Is that what you're --
Q. Well, I'm -- the argument's been made and you've seen it where -- that it's inconvenient in that you have to carry more stuff than just the -- just the bottle of -- or the can of infant formula.
A. So you're saying not just taking it home from the store but when you go out and about and do --

Q. Right, when you go out and about.
A. Well, for those mothers who are really partying when they've got a brand new infant and they're recovering from birth, they actually do make these tiny little containers, and I do know a lot of young mothers now who take it just for convenience rather than carting powdered around. They're little two-ounce containers, prepackaged of ready-to-feed formula.
Q. In your experience do moms with babies who are one or two months old go out a lot?
A. Hopefully not. The recommendation is to not take a baby that young out and about.
Q. How about the argument of cost, that ready-to-feed might be more expensive than form -- powdered formula?
A. I looked at that in my analyses that were in that manuscript. Back in my day, I think that really was the case. But I was surprised. What I did was I compared five different websites, and at those websites I looked at the prices of what an average neonate would eat in a day, and I compared three different brands of soy formula and three different brands of ready-to-feed -- rather, three different brands of milk formula, and I compared the cost of those for ready-to-feed and for powdered. And what I found was that if you were not totally brand committed and you want to comparison shop, you would not be spending even a dollar a day more to do ready-to-feed instead of powdered. If you used soy, it would actually be less

expensive to use ready-to-feed than powdered. And again, remember, we're only talking about the first two months of life. This is not a long time commitment.

Q. How about the argument that if Mom sees something about bacteria on a label or there's any inference that powdered infant formula is unsafe, rather than turn to the commercially sterile ready-to-feed they will use other products such as goat's milk, Carnation Instant Milk, and other products which are clearly not appropriate for a baby?

A. I know of absolutely no evidence that supports that. Do some mothers use these things inadvisedly? Yes. Does it have anything to do with using powdered rather than ready-to-feed? No. I know of no data, and honestly I think it insults mothers.

Q. Has there been any data on, you know, what mothers know about formula in general? Has there been any study?

A. There actually was a survey, yes.

Q. And who conducted the survey?

A. It was a CDC national survey, so it's a nationally representative survey. And this was a tiny, tiny portion. It was really looking at a number of issues in terms of mothers and infants and what not.

Q. And what was the date of that particular survey? Do you know offhand?

A. It was -- it was a very lengthy survey because it was a very large survey, and it went from later in 2005 through 2006.

MR. RATHKE: Could you pull up Exhibit 157 and to that page that has the table that Dr. Jason will make reference to.
A. And if you could just highlight that top line, that's the key part of this.
Q. That line?
A. No, down -- where it says all, the line that gives the numbers for everybody.
Q. Okay. Well --
A. Actually, I mean, the whole -- from the table top to the bottom of that. I'm sorry. I wasn't clear. So from the top where it says table down to including that one line.
Q. The very top of the table.
A. That's perfect. That's it.

So what they did was they asked in this case mothers of two-month-old infants so exactly the age group that's at risk here, and they asked them about each form of formula, whether they thought it was likely to contain germs or not. Now, this is after the labels started saying this is not sterile. And what they found was that 31 percent, even though ready-to-feed was sterile, 31 percent thought it contained germs. Powdered formula they thought -- 29 1/2 percent thought powdered formula contained germs.

So what this says is almost two-thirds of these ladies, even though that label was on there, they thought powdered formula was sterile. And even though ready-to-feed was

sterile, over 30 percent thought it had bugs in it. Literally more mothers incorrectly thought powdered formula was sterile than correctly knew ready-to-feed was sterile. So maybe it's on that label, but people either aren't reading it or they're not understanding it. But any which way, if the goal is to make sure parents have the information they need, it clearly isn't coming through.

Q. Let's go to Exhibit 96 which is the WHO report again, the 2004 WHO report. Do you see on the screen where it says summary of recommendations?

A. Yes.

Q. And the first bullet point says --

MR. RATHKE: Bring it out.

Q. -- in situations where infants are not breastfed, caregivers, particularly of infants of high risk, should be regularly alerted that powdered infant formula is not a sterile product and can be contaminated with pathogens that can cause serious injury -- or serious illness; they should be provided with information that can reduce the risk. Do you see where it says that?

A. Yes.

Q. Do you agree with that WHO recommendation from 2004?

A. Yes.

Q. All right.

MR. RATHKE: Then go to the next -- next bullet. No,

the -- is that the next bullet? Go to the one just -- the second bullet.

Q. Do you see where it says in situations where infants are not breastfed, caregivers of high-risk infants should be encouraged to use whenever possible and feasible commercially sterile liquid formula or formula that has been boiled? Do you see where it says that?

A. Yes.

Q. And were those recommendations affirmed in the 2006 report?

A. I believe they were, yes.

MR. RATHKE: Would you pull up Exhibit 111 which is the 2006 WHO report and go to that page which is Roman numeral 19. Go to the top of the page so they can see the heading. Okay. Recommendations. And then go to the third bullet point and call that out.

Q. The 2000 (sic) WHO report makes this recommendation: Review and revise product labels as appropriate to enable caregivers to handle, store, and use the product safely and make clear the health hazards of inappropriate preparation. Do you see where it says that?

A. Yes.

Q. Do you agree with that recommendation?

A. You know, I think it is so nonspecific that I'm not sure what they're telling anyone to do.

Q. Do you think that the label in this case that we reviewed a

few minutes ago makes clear to the consumer the health hazard of inappropriate preparation?
A. No.
Q. Why not?
A. It implies that if you follow the directions on that label that powdered formula is safe for your baby, and that is simply not the case.
Q. Exhibit 89. Exhibit 89 is a letter from the IFC to the FDA dated June 20, 2003. Do you see that?
A. Yes.
Q. And the letter talks about in the second sentence --
MR. RATHKE: Hold on. Stop.
Q. -- about labeling options. Do you see that?
A. Yes.
MR. RATHKE: And could you turn to page 4 of that exhibit. And highlight the first two paragraphs under rationale.
Q. The IFC states to the FDA that with any label-based initiative, truly ancillary information needs to be avoided. It is critical that the label is not so overcrowded that really important information would be missed. Do you see where it says that?
A. Yes.
Q. Do you regard providing information to infants -- or to parents about the possibility of a pathogen as truly ancillary?

A. I would call it truly important.
Q. Then the second paragraph says providing additional, detailed preparation and handling information on the product label beyond what is currently provided may be difficult to absorb and in the absence of that understanding may be unduly alarming. This includes the use of the term not sterile.
Would you -- do you agree with the IFC's position at that time that putting information that the formula is not sterile is unduly alarming?
A. I do not agree with that, no.
Q. And then it says in addition to potentially causing unnecessary alarm, quote, not sterile, unquote, may cause less careful preparation and handling of the formula resulting in a less safe product being fed to the infant. Do you see where it says that?
A. Yes.
Q. Do you agree that adding language about being not sterile would cause less careful preparation?
A. I don't even understand the logic of that.
Q. Let's go to Exhibit 101.
MR. RATHKE: And just blow that up momentarily.
Q. You'll see that this is an e-mail to a number of people including people who are employed by Abbott coming from the IFC and that it encloses for revision -- enclosed a copy of an IFC educational brochure which was sent to the FDA on September 13.

Do you see where it says that?
A. Yes.
Q. And then let's go to page -- let's go to the next page. And do you see that the enclosure is a letter to a Jeffrey Farber and it regards the recommended International Code of Hygienic Practices for food for infants and children? Do you see that?
A. Yes.
MR. RATHKE: Go to page 4 of the exhibit. I'm sorry. I'm sorry. Go to pa -- oh, yeah, you're right. To conclude, the paragraph beginning with to conclude, second to last paragraph. You got it.
Q. This is a letter from the IFC, and it states to conclude, we are aware of the effort to require formulas to be labeled as may contain pathogens. We do not believe this is appropriate and urge you not to recommend this because breastfed infants are also commonly exposed to pathogens. See where it says that?
A. Pardon?
Q. Do you see where it says that?
A. Yes.
Q. Do you understand IFC's logic in making that point and argument?
A. Well, their next sentence goes on which I know of no data to support.
Q. But do you see any connection with the possibility that

breastfed infants are exposed to pathogens relating to the label for powdered infant formula?
A. Oh. No, no. Well, I do in that I think you need to always inform a parent. I mean, this is a little bit like when a child's called on doing something wrong, they point their finger in saying, you know, he did something naughty too. But no, I don't think it has any direct relevance to labels.
Q. Let's go to Exhibit 118. And I believe you'll see that this is an e-mail from IFC to various individuals employed by the formula companies including the first two being employed by Abbott. And it attaches IFC comments and attachments sent to a Lou Valdez. Do you see where it says that?
A. Yes.
Q. Could you go to the next page. And you'll see that this is a letter to Mar -- excuse me, Mary Lou Valdez of the United States Department of Health and Human Services. Do you see that?
A. Yes.
Q. Referencing a January 2005 meeting with the IFC. Do you see that?
A. Yes.
Q. And then would you go to page 4 of the exhibit. On the very last bullet point where it starts out there is nothing to be gained, do you see where it says there is nothing to be gained -- they're telling the federal government -- by

unnecessarily alarming parents and caregivers in the home by adding disturbing information to the label that would only distract from the important instructions already given there as to the safe preparation and storage of infant formulas? Do you see where it says that?

A. Yes.

Q. Do you agree that adding information about the poss -- the risk of a pathogen would be unnecessarily alarming parents?

A. No.

Q. Do you have any idea or opinion as to why Abbott wouldn't either market their powdered infant formula to older infants, avoiding especially neonates, or provide the additional information about the risk of pathogens? Do you have any opinion as to why they would do that?

MS. GHEZZI: Objection, Your Honor. Foundation.

THE COURT: Sustained.

MR. RATHKE: I have nothing further.

THE COURT: Why doesn't everybody take a stretch break, and then we'll have the cross-examination.

Please be seated.

CROSS-EXAMINATION

BY MS. GHEZZI:

Q. Good morning, Dr. Jason. Can you hear me?

A. Yes, I can.

Q. Okay. Mr. Rathke asked you yesterday if you were being

compensated for your work in this case. Could you tell -- could you tell -- and you said yes. Could you tell the jury what you're being paid by the hour for your trial testimony today?
A. I believe -- I don't know exactly, but it's either seven or nine hundred dollars an hour because I was told this was going to be horrible.
Q. Well, do you remember preparing a addendum to your report where you demonstrated that -- or you listed that court testimony was $1,200 an hour?
A. No, but I'm glad if that's the case. I'll go back to that.
Q. Okay. And does the $1,200 an hour include the time that you sit around?
A. My CFO says it should. I don't plan to do that. We have to discuss that when I get home.
Q. Okay. And on this fee schedule, your minimum for testifying per day is $6,000.
A. I believe you.
Q. So yesterday you would charge $6,000 because that's your minimum, and today you're going to charge $6,000; correct?
A. If that's what that comes to, yes.
Q. And the person who is paying you is plaintiff's counsel; is that correct?
A. Yes.
Q. And since you've been working with plaintiff's counsel doing legal cases on E. sakazakii, you've been paid over a

quarter of a million dollars; is that right?
A. Over the last eight years, that sounds like about right, yes.
Q. And what percentage of the money that you bring to your family business with your husband is generated by you?
A. I honestly don't know. Pr -- I think we're fairly even split.
Q. And what percentage -- and what percentage of the work that you do for the family business is related to legal cases?
A. Varies from year to year. This last year with this case and another, I would say about 50 percent or so. Most years it's much less than that.
Q. Because cases might not be going on. They might be in hiatus?
A. That, and, you know, when I'm asked to do epi studies, that will vary from time to time.
Q. So you've been -- as you just said been paid over an eight-year period for work in legal cases related to E. sak?
A. Yes.
Q. And this case was filed in 2010?
A. I don't know when this case was.
Q. Now, you started working on your manuscript or your paper for Pediatrics after you were hired by attorneys; isn't that correct?
A. Yes.

THE COURT: Miss Ghezzi, just so we don't leave a misimpression with the jury, you can tell by the caption that the case was filed in 2011.

MS. GHEZZI: Oh, I'm sorry, Your Honor.

THE COURT: That's okay.

MS. GHEZZI: It's been a long day already.

THE COURT: I understand.

MS. GHEZZI: 2011.

BY MS. GHEZZI:

Q. Now, the article that you talked about referred to in Pediatrics, that's the first paper you ever published on E. sak; correct?

A. Correct.

Q. And before you started working for plaintiffs' lawyers, you never had anything to do with E. sak; right?

A. Correct.

Q. And your article is six and a half pages long; right?

A. I would have to look. 3,000 words.

Q. Okay. Do you doubt me that it's six and a half pages long in the article --

A. No.

Q. -- I mean in the magazine?

A. No.

Q. Okay. And there is nothing new in that article in terms of new scientific data. In other words, I think you referred to it

as a literature review, and you did a --
A. No, no, actually I did not refer to it as that, and yes, there is new information. Those analyses had never been done before.
Q. Right. But you analyzed data that other people had already collected.
A. Many retrospective studies do that. That's the essence of a retrospective study.
Q. Exactly. So that's what you did here.
A. Correct.
Q. Okay. Now, your background and education is as a pediatrician; correct?
A. As well as an immunologist, epidemiologist, and infectious disease person, yes.
Q. Okay. You don't have a degree in epidemiology, do you?
A. I have my fellowship training in the EIS program which is a training program.
Q. Yes, but I asked you you do not have a degree in epidemiology, do you?
A. No, I do not.
Q. Okay. So your degree is as a pediatrician. You have a medical degree as a pediatrician.
A. Well, you don't get degrees at that level of training. That's why I'm pausing. You don't get a degree for a fellowship.

Q. Okay. I'm asking you --
A. Those are not degreed training programs.
Q. Excuse me. I'm asking you do you have a degree, a medical degree, and your specialty is pediatrician?
A. Yes.
Q. Okay. Now, you're not an infectious disease doctor; right?
A. No. I am an infectious disease doctor.
Q. Are you board certified in infectious disease?
A. I have not taken the ID boards, no.
Q. Okay. And you've never treated a patient with an E. sak infection; correct?
A. I have not, no.
Q. And you've never participated in an E. sak investigation when you worked at CDC for over 20 years.
A. No.
Q. And none of your work at the CDC had anything to do with E. sakazakii, did it?
A. I would not have taken my first case if it had. That would not have been ethical. No.
Q. So the answer is no.
A. The answer is no.
Q. Okay. And the vast majority of your career at CDC you worked on the AIDS virus.
A. Correct.
Q. And you said to Mr. Rathke today -- and I'm not going to

belabor it -- but you're not a microbiologist.
A. Correct.
Q. Right? And you're not an expert in the microbiological or analytical methods that relate to the detection of E. sak, are you?
A. I am in terms of complex sampling designs but not in terms of this organism.
Q. Right. So the answer to my question is you're not an expert in the microbiological or analytical methods that relate to E. sakazakii.
A. The analytical method of the testing plan I would have expertise but not in terms of the microbiologic aspects.
Q. Okay. And you rely in this case on other experts that Mr. Rathke and his firm have hired; correct?
A. In terms of the microbiologic testing in the factory, yes.
Q. And so you rely on Dr. Farmer for one; right?
A. I don't think there's anything Dr. Farmer had that I did. Dr. Donnelly and Dr. -- Drs. Donnelly, yes.
Q. Well, when you have questions about microbiology, you call or write to Dr. Farmer, don't you?
A. Among other people.
Q. Right. But you --
A. Totally aside from E. sak, of course.
Q. Right. But in this case if you have a microbiological problem or question, you ask Dr. Farmer.

A. Sometimes I do.
Q. Okay. Now, I don't know if -- I'm not going to waste the time to start putting things on unless I have to, but one of the slides that was put up was this slide that talks about -- or that just mentions E. sakazakii first identified in 1980 by Jim Farmer. You remember that slide?
A. I do.
Q. Okay. Now, Dr. Farmer did not discover E. sakazakii, did he?
A. He characterized E. sakazakii, yes.
Q. Right. So the answer to my question is he didn't discover it.
A. No, and I didn't say he did.
Q. I know you didn't. But the slide said he identified it, right, and that doesn't mean he discovered it, does it?
A. Actually that's not my slide. Well, I guess -- I don't remember if I presented that slide, but no, he did not discover it.
Q. Okay. Now, he did find it in his dog's water bowl in 1980; right?
A. So he says, yes.
Q. Yes. And his dog wasn't fed powdered infant formula, was he?
A. Nor did he necessarily have the strain that causes infection in infants.

Q. Okay. Well, nobody figured out what the strain was because nobody typed it; right?
A. Correct.
Q. So you don't know what it was and neither does he; right?
A. There are probabilities, and given what's known about that strain, it is highly unlikely it was ST4.
Q. You do not know what it is.
A. A hundred percent certainty, no.
Q. Okay. Do you know what it is 98 percent certainty?
A. I know I'd give you 98 that it is not ST4.
Q. But nobody tested it.
A. Right. Could not be tested back then.
Q. Now, you've never sampled E. sak in a manufacturing plant, have you?
A. Actually I should take that back. I don't know that it's not tested. I don't know what isolates they had in the lab that tested things.
Q. Okay. So you're correcting your answer, and the answer is you don't know.
A. That I don't know if it was tested for ST4.
Q. Right. Okay.
A. Or any ST typing.
Q. So you never -- have you ever -- now, you did say you're not an expert in manufacturing I believe when Mr. Rathke asked you; correct?

A. That I am not an expert in man -- correct.
Q. Right. And you've never sampled E. sak in a manufacturing plant, have you?
A. No.
Q. Right. And you never sampled E. sak in any setting.
A. No.
Q. And you've never looked at it under a microscope.
A. That may not be the case actually, but certainly that's not my expertise.
Q. You've never cultured E. sak.
A. No.
Q. And you've never done any DNA-based PCR testing of E. sak, and you refer to it as polymerase chain reaction; right?
A. Correct.
Q. Okay. You've never done that.
A. Not on E. sak, no.
Q. Okay. And you're not an expert in Abbott's ////////// ////////// testing of E. sak, are you?
A. No.
Q. And you've never done any RiboPrinter testing on E. sak; right?
A. No.
Q. And a RiboPrinter -- do you know what a RiboPrinter is?
A. I do.
Q. Okay. What is a RiboPrinter, please?

A. It is basically doing ribotyping, and no, I have not done that.
Q. And what's ribotyping for the jury?
A. It is another genetic testing technique.
Q. Okay. Now, you've never performed a study on the sensitivity of any particular E. sak testing method, have you?
A. No.
Q. And you're not an expert in the CDC's testing methods for E. sak, are you?
A. No.
Q. And you don't even know what kind of tests the CDC did in this case on the -- on the can of formula that they got from the hospital that collected it from Jeanine's mom.
A. That's not quite correct. I do have -- I read literature on CDC's approach to testing these. What I was not able to get information on was how much of that can they tested and the details. So in other words, most of the time they don't test all the material. They sample it. And I don't know whether they sampled it or tested the whole can.
Q. Do you know how much they tested?
A. No, that's the part I don't know.
Q. You didn't see that document produced in this case?
A. I did not see any document that told me what they actually put into culture.
Q. Okay. So you don't know that there's a CDC record that

says that they tested 111 grams from that can of powder.
A. What I'm not certain of is is that all they tested. I did see they tested that much of it.
Q. They could have tested even more.
A. They could have.
Q. Yeah. And as a matter of fact, that can was 12 -- 12.8 ounces; correct?
A. I believe so, yes.
Q. Okay. And Jeanine Kunkel was fed less than 1 ounce; right?
A. One to two ounces, yes.
Q. No. Less than an ounce. How many feeding -- how many -- how many grams are in a feeding? Do you know?
A. You mean of the powder.
Q. Yes, yes.
A. Oh, yes. Okay. Yes, that would be the case.
Q. So she made up 3 bottles, and there are 9 grams for each if you're going to make a 2-ounce bottle, so she made up bottles with 27 grams out of that can; right?
A. Correct.
Q. Okay. So the vast majority of the powder was still left in that can; right?
A. Yes.
Q. Okay. And you're not an expert in the FDA's method for E. sak testing, are you?
A. No.

Q. Right. And you've never performed any sensitivity studies on the FDA's testing methods for E. sak; right?
A. Correct.
Q. And you aren't here criticizing the CDC's testing method or the FDA's testing method on the powdered infant formula that they collected specifically for this case related to Jeanine Kunkel, are you?
A. I'm not sure what you mean by criticizing. I don't believe it was adequate to prove -- to rule out her having gotten infection from that formula.
Q. Okay. Notwithstanding the fact that you don't even know how they do it.
A. I know how they do it. I've never done it myself, but I have read their documents of what they did.
Q. How do they do it? How does the FDA do it? What did they do in this case?
A. You mean in t -- well, let me put it this way. I do know what they -- that they did sampling. I do not know the details of their culturing techniques, and I defer that to the other experts.
Q. Okay.
A. But I do know what they tested could not possibly detect an isolated cluster of this bacteria.
Q. And you say that based on the Jongenburger article; right?
A. I base that on the Jongenburger article as well as other

evidence that the contamination from this organism is clustered.
Q. Okay. And other than your belief that it's clustered and the Jongenburger article, you have absolutely no other basis to criticize the FDA's method, do you?
A. There is other evidence that it's clustered. There are other researchers that have showed it's clustered, so it's not a belief that it's clustered. There is evidence that it's clustered.
Q. Okay. And apart from that, you don't have any other reason to not believe the FDA's testing; right?
A. Other than that, the play was fine for Mrs. Lincoln. No, I don't.
Q. Okay. Do you know -- can you -- do you know what the analytical method was the FDA used in this case?
A. I defer to the experts in that.
Q. Okay. So the answer is you don't know.
A. (Witness nodded head.)
Q. Right? It's okay if you don't know.
A. Not in detail, no.
Q. Okay. And you've never designed any kind of microbiological testing protocol for powdered infant formula yourself, have you?
A. No.
Q. And you've never isolated E. sak in any powdered infant formula yourself.

A. No.
Q. And you've never performed any empirical study, experimental study, to try and determine the frequency of E. sak in powdered infant formula yourself; right?
A. (Witness nodded head.)
Q. Okay. And you have no expertise in the design of how to make powdered infant formula; right?
A. Correct.
Q. Okay. And you're not an expert in Abbott's manufacturing techniques.
A. No.
Q. And you're not -- you never designed an infant formula manufacturing process.
A. No.
Q. You never conducted a plant audit.
A. Nope.
Q. You're not an expert on Abbott's Casa Grande, Arizona, manufacturing facility where this batch was made; right?
A. Correct.
Q. Okay. You don't know the layout of it. You don't know where the equipment is; right?
A. I don't recall knowing at this point. I may have seen a diagram, but I don't remember it.
Q. Okay. And you testified about some drains, and Mr. Rathke referred to them as drains in the dryer. Do you remember that?

A. In the drying area.
Q. In the drying area, not the drying equipment; right?
A. I don't know one way or another if it's in the equipment.
Q. You don't know where they are?
A. I -- the -- where the environmental samples were taken, I don't know the specific location.
Q. So you don't know that the samples were taken from down a floor drain; right?
A. From Dr. Donnelly's report, that is what I would gather, yes.
Q. Okay. Let me just real quick because I think Mr. Rathke ended with some of these documents called IFC documents, right, you were never a member of the IFC certainly?
A. No.
Q. Right? Never worked for the IFC?
A. No.
Q. You never participated in any IFC meetings?
A. No.
Q. You weren't part of any IFC discussions?
A. No.
Q. You have no idea what Abbott's position was with respect to anything connected to IFC?
A. No.
Q. Now, you talked a little bit about food labeling. You've never designed a food label in your life, have you?

A. No.
Q. And you've never been consulted by any company to design a food label for them?
A. Nope.
Q. And certainly not any infant formula company.
A. I have not, no.
Q. Or any milk powder formula company?
A. No.
Q. Or cereal company?
A. No.
Q. Or pasta company; right?
A. Correct.
Q. Okay. And you've never designed any warning label.
A. No.
Q. Okay. And you're not an expert in FDA regulations on infant formula labeling, are you?
A. You mean the design of the labeling?
Q. On labeling.
A. Can you say that a different way?
Q. Well, you're not an expert on FDA regulations that deal with labeling for powdered infant formula.
A. I was not involved in it, no. I've read some of their material.
Q. I'm asking you if you're an expert in it. I mean, you read some materials. Are you an expert in FDA regulations in

labeling for powdered infant formula?
A. No.
Q. Now, you understand that infant -- you're not a neonatologist; right?
A. Correct.
Q. And a neonatologist is a doctor that specializes in newborn babies.
A. Correct.
Q. Okay. And you understand that infants have innate immune systems; right?
A. Yes.
Q. And if they didn't have immune systems at birth, they wouldn't survive; right?
A. Well, that's not completely true. Actually that is my area of expertise. And infants are born with what's called severe combined immunodeficiency, and they do survive for short periods of time in part because they have the mother's -- assistance from the mother's immune system.
Q. Yeah. So their immune system is developing in utero. While the mother is pregnant, a baby's immune system is developing in the mother. Right?
A. No, it's not that their immune system -- their immune system is to some extent, but until they come in contact with organisms, that's when it truly develops. What they get from the mother is passive acquisition of her maternal antibodies,

not that it's developing those antibodies in utero.
Q. As soon as a baby is -- if a baby is in a hospital for a couple of days, it's going to be colonized with some bacteria from the hospital. You understand that; right?
A. Yes, I do.
Q. And you understand that as soon as a baby starts eating some food that it's got bacteria in its system.
A. Well, if it's ready-to-feed by definition, if it's sterile, no. But yes, as we -- you know, I mean, I talked about that a bit earlier, so I think we both agree on that.
Q. No, we don't really. So let's talk about that. Ready-to-feed is not a sterile product; right? Sterile -- sterile water doesn't have any microbes in it. It doesn't have any organisms in it. It's sterile; correct?
A. I believe commercially sterile means that it doesn't have spores, and other than spores, viable bacteria should not be in there.
Q. And why do you think that commercially sterile means that it doesn't have spores? Where did you read that? What's your authority for that?
A. From the literature on what the definition of commercially sterile is versus sterile.
Q. And what authority is that?
A. I believe some FDA documents and probably some WHO documents.

Q. Can you point me to a single one?
A. Not at this moment, no.
Q. Okay. Now, you understand that there have been invasive E. sak infections in infants where the source of the infection was not powdered infant formula; right?
A. There have been cases where the source has been undetermined, and there have been, as of 2010, 7 cases in infants who have not received powdered infant formula.
Q. Okay. Well, those are your numbers. That seven is your number; right?
A. Correct.
Q. Okay. Okay. So the answer to my question is -- let's see if we can get an answer to that question. There have been invasive E. sak infections in infants where the source of infection was not powdered infant formula; correct? We know that because the baby had no contact with powdered infant formula.
A. Correct. And I will be the first to say there's at least seven cases where that's the case, a very low percent but a real percent.
Q. Okay. And you list some of those cases in your literature review.
A. I hope I list them all.
Q. Well, you list some of them in your manuscript; right?
A. I hope I list them all in my manuscript.

Q. Okay. Well, now, we can talk about that a little bit later, but including infants who were only breastfed, you had seven infants in your supplement to your article who were only breastfed and who had invasive E. sak infections.
A. Actually there were seven who had not received formula. Of those, four had received ready-to-feed and breast milk, and three had received only breast milk.
Q. Okay. You clumped them together as seven.
A. I had seven that had no contact with powdered infant formula.
Q. Correct. So you would agree with me that for those seven infants powdered infant formula was not the source of their invasive E. sak meningitis.
A. I would agree with -- well, I would agree with you on the caveat that it's conceivable they had exposure, but those I would consider not related to powdered infant formula.
Q. Okay. In 2008 how many formula-fed babies in the United States were fed powdered infant formula? Do you know?
A. No. I would love to know that. I cannot get solid data on what proportion or number of infants got what types of formula. And I've said this before at depositions. If there is information, I would love it if it would be shared.
Q. Uh-huh. Well, the U.S.D.A. puts it out. Have you not seen the article from the U.S.D.A.?
A. No. I would love -- actually I would love to see that.

Q. I think if you Google it, you could actually --
A. I've done a lot of Googling, so I would love it if you have that reference.
Q. Now, Mr. Rathke showed you the World Health Organization report from 2004. And what it says in there -- and I don't think he showed you this. But it also says not all infants with -- and I apologize if I forgot. But -- if he did show it, but it says not all infants with E. sakazakii infection have been exposed to powdered infant formula. And E. sakazakii infections can also occur in adults; right? Thus, although an environmental source of E. sakazakii infection other than infant formula has not been strictly identified, other sources undoubtedly exist. That's what it said in the World Health report which was a draft report, by the way, in 2004; right?
A. Correct.
Q. Okay. And you would agree with that statement.
A. I've never disagreed with that statement.
Q. Okay. Now, you've never tried to determine what the sources of those other infections are that are something other than powdered infant formula; right?
A. I've not been in a position to do that.
Q. Okay. Well, part of the reason why you wrote your article in 2012 was to sort of inform people and -- so they could be on the watch for invasive E. sak bacteria for their newborns; right?

A. Correct.
Q. Okay. And so if you've known since 2004 that there are other sources, undoubtedly other sources exist that can infect infants, isn't that something that you would want to know that would also be of use to the medical community and the families that you're trying to educate?
A. I'm not sure I understand the question. I -- this is something that I would be doing? I don't -- I don't investigate cases directly.
Q. Well, you investigated ca -- the same way that you investigated cases that you said came from powdered infant formula, you could investigate cases that came from the environment; right? You just didn't look for any of that data, and you didn't do any of those analyses.
A. Oh, that is absolutely not true.
Q. Okay.
A. I -- in fact, no, that is so completely not true. Every single case that I examined I obtained -- I attempted to obtain all the information I could obtain. Those cases, interestingly, are far more likely to be published because they're interesting. They're very, very different. Unfortunately, those publications have not done any investigation, so there are no data or information. I have contacted authors, and basically no epidemiologic investigation was done; no microbiologic testing was done. It is not that I didn't attempt to get it. I tried

very hard. It simply did not exist.
Q. Yeah. So it's very difficult to make the argument that the only source of E. sak comes from powdered infant formula when nobody's doing the testing and analyzing any of the other environmental sources that exist and that cause E. sak in -- E. sak infections in infants; right?
A. Well, that's kind of a roundabout way of -- you complain that investigation isn't adequate in cases, and then you turn around and say, well, it's not adequate, so you shouldn't be blaming powdered infant formula. Investigations are done. They are incomplete. And I have never said every single case is in an infant who received powdered infant formula.
Q. Okay.
A. I do think with strain typing it's going to be very interesting to see where that handful of other cases -- what they're associated with, but you can't do that if they appear as a case report two years after the fact.
Q. Now, there are many cases of E. sak infections in adults as well, and you referred to that a little bit in your direct examination; right?
A. No, incorrect. There are some rare cases of cronobacter infection in very elderly, hospitalized, debilitated adults. There has never, to my knowledge, been a case of cronobacter meningitis in an adult, and it is not something that's in a normal, everyday, healthy human being. It can sometimes

colonize tracheas if somebody's intubated. But this is not an organism that causes severe infection in even elderly immunocompromised adults.

Q. Okay. Well, Dr. Jason, I didn't ask you if there was E. sak meningitis in adults. I asked you whether or not there was E. sak infection in adults.

MR. RATHKE: Move to strike the comment.

THE COURT: That's exactly what you asked her, Miss Ghezzi, whether it was E. sak --

MS. GHEZZI: I didn't ask her about meningitis.

THE COURT: Okay. Why don't you just ask another question.

MS. GHEZZI: Your Honor, is that up on your screen, what I just put up? Can you see that?

THE COURT: I just look at it on the big screen.

MS. GHEZZI: Oh, okay. This is Exhibit 1018.

BY MS. GHEZZI:

Q. I'm going to ask you to look at the top table 2 right there.

A. Okay.

Q. You recognize this table, don't you?

A. I do.

Q. Okay. And what this shows is this sh -- and where does it come from?

A. This comes from one of the reports, one of the WHO reports.

Q. Right. The World Health Organization reports; right?
A. Correct.
Q. And they did -- they did a survey of enterobacter sakazakii laboratory confirmed reports by age group. Do you see that?
A. I see that. That actually, though, isn't a survey they did. That is not a survey done by WHO.
Q. Let's take a look at this. So the top one is from 1999 to 2007; right?
A. Correct.
Q. Okay. And the under-1-year-olds, there were 15 of them; right?
A. Correct.
Q. And then there are -- it says 1014, but nobody is 1014 years old, so there's supposed to be a little dash in there.
A. Correct.
Q. Just like at the bottom; right? So from the 10-to-14-year-olds there were 7 people --
THE COURT: Now wait a minute. There's supposed to be a little dash in there? You're testifying.
MS. GHEZZI: No, it's right on the next one, Your Honor. Right below it you can tell that they just didn't put the dash in.
THE COURT: Well, you're testifying about that.
MS. GHEZZI: I'm asking her if she agrees with that, and she said yes.

BY MS. GHEZZI:
Q. So how many children -- and you know what? Let's go to -- since there is a dash in the second one, let me do this. Let's look at table 3. Do you see that, Dr. Jason?
A. Yes.
Q. Okay. And it says E. sak laboratory confirmed reports by age groups for England and Wales from 1999 to 2007. See that?
A. Correct.
Q. Okay. And in the under-1-year-olds it shows 14; right?
A. Correct.
Q. And in the -- it goes down the list, but let's go down to the 10-to-14-year-olds. They're 8. And then in the 15-year-olds to 44-year-olds, there are 114; right?
A. Correct.
Q. And then from the 45-to-64-year-olds, there were 222. And then in the 65-to-74-year-olds, there are 179. And then 75 years plus there are 202, and unknown there are 22; right?
A. Those are the numbers.
Q. Okay. And if we take out the unknowns, the percentage of E. sak confirmed reports by age in the less-than-1-month-olds is 1 percent of that total. Do you agree with that?
A. Yes.
Q. Okay. Now, you agree that the -- oh, sorry. You agree that the incidence of E. sak infections in the United States annually are -- or it's even worldwide; you tell me -- four to

six, four to six cases a year?
A. Are we going to talk about what this table's actually showing or not?
Q. I'm going to -- I ask the questions.
A. Okay.
Q. And so when I'm finished with it, then I should take it off. Thank you.
A. Okay.
Q. And let me just go back to -- so these adult patients, all these patients in that study --
A. Now what study are we talking about?
Q. I mean in the World Health Organization document we just looked at, okay, those were people who were -- where they had laboratory samples who were -- and they were tested and it was tested to be E. sak; right?
A. They had -- these people -- these are not people for one thing. These are reports, not people. These are from a surveillance system in the UK and Wales. And what they do is look at positive lab results. In the two tables you showed me, they were blood culture results. They are -- and I've talked to people who run those reporting systems. These are all hospitalized patients.
Q. Okay.
A. And if you look at that breakdown, you'll see the number increases with age. It does not mean they have clinical

illness. What it does mean is that they have come up with positive blood cultures.
Q. Yeah.
A. And if you divide those numbers by the numbers of years covered, you'll see that it is exactly as I said, very rare. It does happen in hospitalized patients. However, the diseases are not as severe. That surveillance system does not look at the severity of disease. It simply records --
Q. What are the --
A. Nor does it know for certain if it's the same person coming more than one time into the hospital.
Q. Uh-huh.
A. So all you're looking at there are lab results.
Q. And the same is true for the under-one-month-year-old (sic).
A. Which is why I --
Q. Right?
A. You know, obviously that is totally -- that is not part of what I studied.
Q. Right.
A. That is simply lab results.
Q. You -- well, they're lab results that have to do with people; right?
A. But you don't --
Q. There are people attached to the lab results.

A. Absolutely.
Q. Right, doctor?
A. But --
Q. And let me just say this.
THE REPORTER: I need one at a time.
Q. I'm sorry. And when you're talking about elderly, you know, people who are from the ages of 44 -- I mean, we can argue about it, but people from the ages of 45 to 65 are not really classified as elderly people, are they?
A. As I said, if they are hospitalized, immunocompromised by some underlying disorder, and as you look at that table, the numbers increase with age because increasingly you find people hospitalized with immune deficiency from primary or secondary causes.
Q. Right.
A. And I am not saying that the people are not important. Of course, they are. What I'm saying is you cannot take those numbers and translate that into saying this many people have this.
Q. That's fine. But here's what you can translate it into. Those elderly people or those people who were from 10 years old to 65 years old, they didn't get E. sak from eating powdered infant formula, did they?
A. Absolutely.
Q. Okay.

A. As I say, cronobacter is in a number of things, and older people eat other things, and they have different types of cronobacter.
Q. Okay. And the -- the CDC tries to test environmental sources when it can; right?
A. Yes.
Q. Okay. And the CDC believes that it is important to test potential environmental sources other than powdered infant formula.
A. Correct.
Q. Right. And the CDC in the person of Anna Bowen wrote to you personally fairly recently informing you that the CDC had data suggesting that many other vehicles for cronobacter infections exist, didn't she?
A. That's not quite accurate. What she wrote was that they were looking into that possibility.
Q. This is Exhibit 1020.
A. And your question?
Q. Can you see it, doctor?
A. I can.
Q. Okay. And what this says is -- sorry for that mess. It says, "I do think your message is appropriate and important. However, I have had trouble convincing anyone that we have irrefutable evidence of intrinsic contamination recently, and I am actually working with some data now that suggests many other

vehicles for human cronobacter infections exist. I know that FDA has also been working on other hypotheses." Right?

A. That is correct reading, yes.

Q. Okay. And then she says -- at the end of that she says, "Given all of this, I am afraid that your paper might be unrecognizable after passing through the clearance chain."

So let's just sort of discuss what that means. You had asked Anna Bowen if she would coauthor your manuscript with you; correct?

A. Correct. I asked her if she'd like to do that.

Q. Okay. And she says that -- in the first paragraph right here, "I hadn't forgotten your offer but was mulling over whether I could take up another project now and what CDC clearance and FDA cross-clearance which will also likely be required is likely to do to the paper unless the evidence is extremely clear." Right?

A. That's what it reads, yes.

Q. Okay. And so she declined to be a coauthor.

A. Actually this is actually not all that recent, by the way. This is before the paper came out.

Q. Right.

A. But yes, she did.

Q. Right. It's before the paper came out because you were asking her to be a coauthor.

A. Right.

Q. Now, you have said that invasive E. sak infections are very rare, and four to six per year in the United States comes out to about one in a million births per year; right?
A. That would be correct.
Q. Okay. And do you know how many cases of salmonella sickness there are in the United States per year from food?
A. There are thousands.
Q. And how many are there from E. coli?
A. Thousands.
Q. And how about -- how many are there from listeriosis? It's another bacteria.
A. Hundreds to thousands.
Q. Okay. In terms of whether or not infant formula can be -- well, let me ask you another question because this was sort of in your direct today. Mr. Rathke put up some slide, and you -- your testimony was that E. sak only enters through the mouth; right?
A. It does enter through the mouth, yes.
We're not going to talk about this letter any further?
Q. No.
A. Too bad.
Q. So it can only enter through the mouth. That was your testimony.
A. I did not say only. It enters through the mouth.
Q. Okay. Well, I thought -- I'm sorry. I thought you said it

can only enter through the mouth. Let's talk about where else it can enter. It can enter through any mucosal opening in a human body; right?

A. No.

Q. Okay. Well, it can enter the body through a wound, can't it?

A. You want to give me some references on that? It certainly can be found in a wound, but that doesn't mean it's entering a sterile site in the body.

Q. Do you know -- well, it's found in a wound. And is it your understanding that bacteria -- if you have an opened -- if you have an open spot on your skin that bacteria cannot enter your body?

A. No. My point is if you have an open wound and you come across not the kind of cronobacter necessarily that causes invasive infection but a cronobacter, it may sit in that wound and try to take up residence. It will not be terribly successful.

Q. And if you come across a cronobacter that is virulent and it gets in your wound, it may go in your body and take up residence and cause an infection?

A. I have no idea. I can't think of a single case where that was -- that happened. It has to get to the bloodstream. So you'd have to have an incredibly deep -- this is all so incredibly hypothetical it's almost absurd.

Q. Well, it's found in wounds. It's been -- in the Forsythe article, it's been found in wounds; right?
A. It has been found in wounds, and to get to the bloodstream, you've got to be able to get to a blood vessel. So, for instance, a diabetic -- and I believe these are the wounds where they've rarely maybe, what, two or three times found it in a superficial wound. Unless that becomes -- it's so hypothetical, it's hard to even conceive of it.
Q. Dr. Jason, when somebody has a wound, if there's a cut, does it bleed?
A. Yeah, the blood goes out.
Q. Okay.
A. It doesn't go in.
Q. But bacteria can get in there. We can get skin infections all the time that can develop into something else like staph.
A. This is so exquisitely hypothetical that the probability of this is one in a million.
Q. Okay. You have heard of staph infections, right, that start from the skin and then go all over the body?
A. I have worked on them, and indeed we have staph on our skin every day. It is ubiquitous. It is all over our skin.
Q. Okay. And you agree that there can be cross-contamination of any kind of food. If you've got a can of formula and you open it, as soon as you open it, if there's bacteria around and if there's bacteria on somebody's hand, they can contaminate it;

right?
A. We have talked about this at the depositions.
Q. I'm just asking you is that correct or not. If somebody has bacteria on their hands and they open up a can of powdered infant formula and they stick their hand in there to pick out a scoop and there's bacteria, can the bacteria get from their hand into the powdered infant formula?
A. Hypothetically, yes.
Q. Okay. And even if someone boiled bottles ahead of time, if they take it out of the pan and then they're mixing it with their hands and then they're putting it in the refrigerator and then they're taking it out of the refrigerator and then they're feeding it, they can still put bacteria on the bottle, right, if they have it on their hands?
A. But if it's ST4, it likely came from the powdered infant formula.
Q. Okay. I didn't ask you about ST4 yet. I'm asking you if there's bacteria on hands and it can get -- it can get on the bottle, right, even bottles that have been sterilized when they're put in the refrigerator?
A. That is conceivable.
Q. Okay. And the same is true for nipples. If somebody's boiling nipples and then they touch it and then it's in the refrigerator, same thing. Bottles, nipples, the same thing; right?

A. If people don't follow guidelines, they not only could get -- they could get any sort of extrinsic contamination.
Q. Okay. Now, we know you didn't participate in the investigation of Jeanine Kunkel's illness or the E. sak -- the E. sak illness at the time it occurred in 2008; correct?
A. Correct.
Q. Okay. But the CDC and the FDA and the Iowa Department of Health and the Nebraska Department of Health and Human Services, they all got involved; right?
A. Correct.
Q. Okay. And neither the CDC nor the FDA nor the department -- the Nebraska Department of Health and Human Services nor the University of Iowa who took the samples in the home nor the Iowa Department of Health ever concluded that Abbott's powdered infant formula was the source of Jeanine Kunkel's E. sak; isn't that correct?
A. They did not reach a conclusion, correct.
Q. They reached a conclusion when they tested it and said that it wasn't in the powder that they tested, right, including the can?
A. They reached a conclusion that it wasn't in that portion, yes.
Q. Well, nobody can test the portion that somebody has eaten and digested; right?
A. Absolutely correct.

Q. And that is true regardless of what the bacteria is.
A. That is correct.
Q. And so when people -- when people eat anything -- it could be cereal that can have E. sak in it. It's been found in cereal. It's been found in potatoes. It's been found in tea and spice and all the rest of it. If they've eaten it, you can't test that. And so that's not what testing is all about. Testing is about seeing if there is a possibility that it could have come from that product; right?
MR. RATHKE: Object to the form of the question.
THE COURT: I don't know what that means.
MS. GHEZZI: I'll withdraw it, Your Honor.
Q. Now, Jeanine Kunkel was treated by a number of patient -- sorry, doctors. She was treated by doctors at St. Luke's Hospital here in town, and she was treated by hospital -- I mean by doctors at the Omaha Children's Hospital; right?
A. Correct.
Q. Okay. And none of those doctors concluded that the source of her E. sak infection came from powdered infant formula; right?
A. It's not the job of a clinician to come to that kind of conclusion.
Q. They didn't conclude it; right?
A. One -- they -- would not even have been an issue they dealt with.

Q. So they didn't conclude it. They didn't reach a medical conclusion about the source of her infection.
A. That's not a medical conclusion.
Q. Well, you're making one, aren't you? You're a doctor. You're making one.
A. I'm doing this as an epidemiologist.
Q. Oh, okay. For which you have no degree.
MR. RATHKE: Object.
MS. GHEZZI: Okay.
MR. RATHKE: Argumentative.
THE COURT: It is argumentative, so it's sustained, but the jury already heard it.
BY MS. GHEZZI:
Q. Now, the testing results you talked a little bit about and we all know, we all -- well, you didn't see them because you weren't shown them, but you've seen them in the documents from the case that the CDC's testing of the can that Jeanine Kunkel used was negative for E. sak; right?
A. Correct.
Q. Yeah. And same thing with the FDA records; right?
A. Correct.
Q. Okay. And you also saw I believe that Abbott's finished product testing of the batch -- and the batch number you might not remember, but I'm going to say it for you because you may see documents -- 61281 -- RE is the batch number -- that batch

was tested by Abbott during manufacturing; correct?
A. Correct.
Q. And you saw the results of those tests, and they were negative for E. sak; right?
A. Correct.
Q. And Abbott tests its product specifically for E. sak; right?
A. Correct.
Q. And it tests its product specifically for salmonella; right?
A. Correct.
Q. And specifically for E. coli; right?
A. Correct.
Q. And along the manufacturing process, it tests its product for any kind of bacteria that it can find before it goes through its purification, pasteurization state which is called SPC, right, plate count? Do you know those SPC tests?
A. I do know that, but you said before pasteurization. Did you mean to say that?
Q. Yes.
A. Okay.
Q. Yeah, they test there too.
A. Yes. I just wanted to make sure you meant that.
Q. Yeah. They test there too. And then they test finished product.

A. Correct.
Q. Okay. And not one of the tests that anybody's ever looked at came back positive for E. sak.
A. On this lot, yes.
Q. On this lot. That's the lot she got.
A. Correct.
Q. And your opinion basically ignores the testing results. You don't -- you don't really discuss it in terms of what's wrong with them. You're relying on the microbiologists for that.

MR. RATHKE: Object to it as argumentative.

THE COURT: Overruled.

Q. Let me just ask you this. The CDC didn't ignore its testing results, did it?
A. I'm not sure what you mean.
Q. They didn't -- they tested it because they wanted to see if there was any likelihood that there was actually E. sak in this product because if there's E. sak in the product, they have a responsibility to make sure that no other -- no other portions of this batch on the market are eaten by anybody; right?
A. That's actually FDA's responsibility, and I think in this kind of testing what you're tending to do is if you have a positive you can go further, a negative is not necessarily conclusive. In a lot of microbiologic testing, that's pretty much the situation you're in.

Q. Okay. Well, a lot of microbiologists would actually disagree with you, and apparently the CDC did because the CDC took absolutely no action with respect to this batch of formula; right?

A. CDC --

MR. RATHKE: Objected to as argumentative.

THE COURT: Now just a second. That's testifying. A lot of biologists -- a lot of microbiologists would disagree with her?

MS. GHEZZI: Okay, Your Honor. I'll withdraw the statement.

THE COURT: Okay.

MS. GHEZZI: It was a question.

THE COURT: Why don't you rephrase it.

MS. GHEZZI: Okay.

BY MS. GHEZZI:

Q. The CDC didn't take any action, did it, with respect to this batch of formula after it found it was negative?

A. They did not, no.

Q. Okay. And the FDA -- well, let me ask you this too. I'm sorry. And I think you went over this, but just so we're clear, there were 79,000 cans sold in the United States. Did you see those records from Abbott?

A. Yes.

Q. Okay. And that amounts to millions of feedings, doesn't

it?
A. Yes.
Q. Okay. And there was not a single other report of E. sak illness from that batch; right?
A. Correct.
Q. And so what the CDC would refer to the Jeanine Kunkel incident of illness is as a sporadic case of illness. That is a single, isolated instance of illness; right?
A. Correct.
Q. And that's different from an outbreak; right?
A. Correct.
Q. And I think Mr. Rathke may have asked you about the outbreak from 2001 in the Tennessee NICU; right?
A. I don't believe he did, but I'm familiar with it.
Q. Okay. He may have said it in his opening. I'm sorry. So there was an outbreak in the United States in 2001 in a Tennessee NICU; right?
A. Correct.
Q. And in that situation there was one child who got an E. sak disease, and there were eight other infants that were colonized but never got a disease. Are you familiar with that?
A. Correct, yes.
Q. Okay. And there's only one other reported outbreak in the United States -- this is in the Bowen and Braden article if you're familiar with it -- and that was in 1989; right?

A. Correct.
Q. And there were -- there was no meningitis, and there were two infants with bacteremia; correct?
A. Correct.
Q. Okay. And so we're talking about 3 infants in the United States from 1989 to 20 -- now we're in 2014 where the FDA -- I mean, I'm sorry, where the CDC in terms of the United States has said, you know, in those outbreaks there was an association with powdered infant formula; right?
A. Correct. I'm not sure what you're asking me. Also these are -- by definition, outbreaks are in hospitalized infants, and powdered infant formula now isn't being used in most places with hospitalized infants. So it's not surprising that you wouldn't expect an outbreak.
Q. Outbreaks -- I mean, the definition of an outbreak has nothing to do with whether or not somebody's hospitalized.
A. The definition of an outbreak is you have to have people in one place to have an outbreak.
Q. Right, right.
A. When people are living at home, that's why they're sporadic cases. You're not going to have an outbreak if there's only one at-risk person.
Q. Okay. And so the only association between powdered infant formula, okay, and E. sak has only been found in connection with an outbreak.

A. I'd say your FDA data on ST4 says that's not the case any longer.
Q. Okay. Let's put aside the ST4. I'm going to get to that; okay? But the only -- and CDC says the same thing. The only -- doesn't it? The only way that they say the association -- there's an association between powdered infant formula and E. sak in infants is in an outbreak situation, never in a sporadic case?
A. I don't know that you can say CDC says that. If you look at their website, I think they do discuss the role of powdered infant formula. But you cannot do an outbreak investigation if you don't have enough numbers to do an outbreak investigation.
Q. Right. If it's a sporadic case and where you don't test the environment sufficiently and you never know where the source is; right?
A. You are not going to do -- by definition, you can't have an outbreak with one case.
THE COURT: Miss Ghezzi, would now be a good time to take our next break? Is that okay?
MS. GHEZZI: Sure.
THE COURT: Okay. Members of the jury, it's almost 20 after 12. We'll be on break until 12:45. Thank you.
(The jury exited the courtroom.)
THE COURT: Counsel, anything we need to take up?
MS. GHEZZI: I don't believe so.

THE COURT: Okay.

MS. GHEZZI: Thank you, Your Honor.

(Recess at 12:18 p.m.)

THE COURT: Please be seated, but before we bring the jury in, how are we going to accommodate this -- doesn't somebody -- doesn't plaintiff have a witness coming in or . . .

MR. RATHKE: Yes.

MR. BOTTARO: Yes, Your Honor. It's Dr. Sherman. He's here. He's ready to go. So I think there's some hope that they'll get done with this witness and then have time for him. And if not, then we will get him in there before court adjourns at 2:30.

MS. GHEZZI: I mean, if he's here and they want to take him now --

THE COURT: Would that be okay with you?

MS. GHEZZI: Oh, yeah.

THE COURT: Because I don't want to cut short your cross.

MS. GHEZZI: Yeah, I'm not going to be finished by 1:30 unfortunately.

THE COURT: No, that's fine. That's not a problem. They didn't exactly put her on in an hour either.

MS. GHEZZI: I didn't hear that but . . .

THE COURT: Oh, I'm sorry. The plaintiffs didn't exactly put the witness on for only an hour.

MR. GHEZZI: Oh, oh.

THE COURT: Yeah.

MR. REIDY: Judge, could I raise one other brief thing which is just -- and I don't think there's any objection to this -- there was another article in the paper and online today about the trial. And so if you wouldn't mind at the end of the day, particularly for the woman who clearly is Facebook-linked to the paper . . .

THE COURT: Yes.

MR. REIDY: That means it pops up in her Facebook every day.

THE COURT: Mr. Reidy, that's a really good suggestion, so thank you, and I will remind them.

MR. BOTTARO: Should I have the witness on the stand or not?

THE COURT: Well, you should have him in the courtroom, and then I'll explain to the jurors what's happening.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

Members of the jury, I just wanted to explain what we're doing. This frequently happens in trials, particularly trials with expert witnesses who are coming from other parts of the country often, so we're going to take a witness out of order. Ms. Ghezzi was not finished cross-examining Dr. Jason, but she was gracious enough to postpone that for a while while

we try and get another witness in to accommodate their schedule. It happens very frequently, and then eventually we'll get back to the cross-examine of Dr. Jason.

So, Mr. Bottaro, who's your next witness?

MR. BOTTARO: Thank you, Your Honor. Dr. Jerome Sherman.

THE COURT: Okay. If you'd please come forward, Dr. Sherman, I'll swear you in. Would you raise your right hand, please.

JEROME SHERMAN, PLAINTIFF'S WITNESS, SWORN

THE COURT: Thank you. Please be seated. You can adjust the chair and the microphones so you can speak directly into the microphones. And would you tell us your name and spell your last name, please.

THE WITNESS: My name is Jerome Sherman, S-h-e-r-m-a-n.

THE COURT: Thank you.

Mr. Bottaro?

MR. BOTTARO: Thank you.

DIRECT EXAMINATION

BY MR. BOTTARO:

Q. Would you please tell the jury where you're from, sir.

A. Omaha, Nebraska.

Q. And what do you do for a living?

A. I am a finance professor at Creighton University in Omaha.

Q. How long have you been a finance professor at Creighton University?
A. I came to Creighton in 1976. I retired in 1999. They asked me to come back in 2005. So I've been there ever since.
Q. And can you give us your educational background, please.
A. I have an undergraduate degree in mathematics, Regis College, Denver, Colorado. I have a master's degree in economics and finance from Memphis State University. And I have a Ph.D. in business administration in which the main areas were finance, quantitative economics, and microeconomics from the University of Mississippi.
Q. And can you tell us your business background.
A. I have approximately ten years in the securities industry, five years as a stockbroker and an owner of a small brokerage firm. Five years I did corporate finance and research for two regional brokerage firms. I also spent four years on the board of directors of New York Mortgage Trust Company located in New York, listed on the New York Stock Exchange, and I was the chairman of the audit company.
Q. And have you published any articles that would be important for the jury to know about as relates to the testimony you're going to provide here?
A. I have published articles. I have probably nine to ten published articles. I would say relative to the one today, I have one in which I developed the theory of how to determine

discount rates, and it was published in the Creighton Law Review.

Q. And by discount rates, does that have another term that we use in the court system?

A. Yeah. I will be talking about present value quite a bit, and so we're going to be talking about present value, and so I have to have a discount rate or an interest rate. The terms are synonymous. And so that's what I did.

Q. And has that article at all been cited as authoritative by any courts in the United States?

A. That article was cited by the United States Supreme Court Justice Stevens in which it's cited -- this was one of two methodologies to determine discount rates in these types of cases.

Q. And you've testified in personal injury civil cases such as this before; is that correct?

A. Correct.

Q. For both plaintiffs and defendants?

A. Correct.

Q. And you have been requested by me or my firm in the past to provide testimony in personal injury cases; is that correct?

A. Correct.

Q. And Mr. Gray who's one of the defense attorneys here for Abbott, have you been asked -- called upon by any members of his firm to be -- to testify on behalf of any of their clients?

A. I have.
Q. And am I correct that we have asked you on the plaintiff's side to make some projections of economic loss in the Security National Bank and Jeanine Kunkel case; is that correct?
A. Correct.
Q. And that's what we're here today for.
A. Correct.
Q. And you've been asked to provide two different projections; is that correct?
A. Correct.
Q. Would you tell the jury what those two are?
A. One would be the present value of the loss of her earning capacity. The other would be then the present value of the life care plan.
Q. And let's talk first about the loss of future earning capacity. And if we'd turn to Exhibit 169 --
A. Correct.
Q. And we're going to start -- I'll ask you this. What information is necessary to make economic projections for Jeanine Kunkel or someone like Jeanine Kunkel in a case like this?
A. In this type of case, it would be the date of her birth which was April 14, 2008, that she's currently 5 years of age.
Q. We're pulling up page 3 of Exhibit 169. Are you referring to this?

A. That is correct.
Q. All right. Go ahead. I'm sorry.
A. And that she has a life expectancy according to the commissioner's 2001 standard ordinary mortality table of 75.95 years. She has a work life expectancy of 43.8 years. And in terms of background, I made the assumption that she would have been at least a high school graduate or a GED and could have earned what an average female could have earned.

The second portion that I'll testify to, I was given the life care plan developed by Lisa Pollard, and I present valued those numbers.
Q. And in both instances for both types of projections, for the loss of future earning capacity and the life care plan, were you provided all of the information necessary for someone in your field to render expert opinions?
A. Yes.
Q. And are your opinions based upon, that you're going to talk about, a reasonable degree of economic certainty?
A. Yes.
Q. All right. And let's go, first of all, then to page 169 -- or Exhibit 169, page 4.
A. Correct.
Q. And what is this for the jury?
A. That basically -- I first determined on the top -- and this is with respect to 2012 lifetime earnings -- that for high

school or GED female, lifetime earnings would be 1,405,936. I increased that then to -- increased it by 2 percent for 2012 which would be the 1,434,650 -- or 055.

Q. And earlier as I understand -- so these projections are not based upon someone that would have a college degree or even a community college degree; is that correct?

A. That is correct.

Q. This would be just a GED or high school; is that correct?

A. Correct.

Q. All right.

MR. BOTTARO: And then could we scroll up a little bit more there, Patrick? There we go.

Q. Now, you talked earlier about present value. Would you explain to the jury what present value means since they have to apply that if they find damages are to be provided in this case.

A. You will see there are two discount rates: 1.82 percent, and the other one is 1.49 percent. 1.82 percent represents the relationship between wage increases and interest rates over a 50-year period of time. So I always make an assumption there will be wage increases, but then the money will be turned around -- by present value, the money will have to be invested today so that in that particular case then I wanted to determine what the discount rate would be.

So over a 50-year period of time, the wage increases -- I'm sorry, the interest rates had been 1.82 percent

greater than the wage increases. Over a shorter period of time, 20 years, that relationship has been 1.49 percent so that the interest rates have been 1.49 percent greater than the wage increases. So I assume that we'll have a certain amount of money. Each year the certain amount is taken out. But I assume that wages will be increased and the money will be invested in intermediate term United States government treasuries with a 3- to 5-year maturity.

Q. And do you have up there for the jury to see your opinions on those two different -- and if you want to look at your computer screen there too and refer to it and you have the stylus pen there if you need to -- if you need to make any circles or anything like that or point. Do you have that pen with you?

A. I have the pen, but I'll just read the numbers.

Q. Okay. All right. So will you tell the jury what -- with the discount of present value -- you're taking the 1.4 -- $1,434,055 up above the lifetime earnings for a woman; is that correct?

A. That's correct.

Q. And reduced it to present value, and then explain what these figures are and what all --

A. The present value of that then in today's dollars, the amount that it would take to replace that income, would be -- at 1.82 percent, it would be 982,503.

The other thing then I have to take out is taxes. So if I take out the taxes of 120,848, that would leave 861,655. And at 1.49 percent, the loss of the high school graduate or GED, the present value would be 1,047,728, less the taxes of 128,871. That would leave 918,857.

MR. BOTTARO: Is everyone able to hear that? I know that sometimes when he looks away from the microphone -- you're okay. Okay.

Q. So those two numbers at whatever discount rate you look at, those two bottom-line dark numbers would be your opinions of the lifetime earning capacities reduced to present value less taxes.

A. That is correct.

Q. All right. Does that complete your testimony for the jury regarding potential loss of future learning -- earning capacity?

A. Correct.

Q. Okay. And the second part you said was present value of a life care plan. And if we'd go then to page 6 of Exhibit 169. Now, first of all, need to understand normally your testimony would come after the testimony of a person that's known as a life care planner; is that correct?

A. Correct.

Q. And who was the life care planner in this case?

A. In this particular case it's Lisa Pollard.

Q. So would you explain to the jury -- normally Lisa Pollard would have already testified as to what she does. Would you

explain what a life care plan is.
A. Basically what she would be doing is she would explain each of these items that she feels is necessary for the rest of the life of this child and then the number of years. Sometimes it might be for five years. Sometimes it might be for ten years. Sometimes it starts at 21 years. All I do is find the present value of what she is saying is going to be necessary.

For example, her first two, I certainly -- she'll be explaining all of these things, but -- and I won't go down through all of them. But basically she's saying there needs to be an evaluation at age 5 for both the mother and the father, one year, at the cost of $200.

Now, if you see there then, I have two different discount rates there. The items on the first part of the life care plan are those items that are associated with medical care services. And then what I have done is I have found the relationship between medical care costs and interest rates. Obviously medical care costs have been rising faster than either inflation or wages.

So the first discount rate that I have is I have it mathematically as a minus .03 percent which basically is saying this, that healthcare costs over 50 years has been slightly greater than interest rates over a 50-year period of time, and that number then is by .03 percent. Over the last 20 years, it's been 05 percent. So in effect, I find present value, but

in reality the math is these numbers are going to be slightly greater than if I just straight multiplied the amount times the number of years. And I'll show you that.

In case of, oh --

Q. He can scroll up or down too if you want him to.

A. Okay. Even take speech therapy. If you take speech therapy, basically the report would say that starting -- I begin at age 5, that for 15 years, the cost would be 12,900. The next number there, the 193,000, I simply take 15 times 12,900. That's straight math.

Then to find the present value of that, you will see that it is -- the present value for those 5 year -- or for those 15 years is slightly greater than the 193,500. It is 193,907. That's how much it would -- how much money would be necessary today to provide that service for those 15 years, and at the end of that period of time, the money would all be gone.

Then with respect to the physical therapy, if you remember I said she has a life expectancy of 75 years. So then the Lisa Pollard report would say, well, then for the rest of her life --

Q. And this is speech therapy, not physical therapy; correct?

A. I'm sorry. Yeah.

Q. Yeah.

A. Then it would cost, for 60 years, 1,350 per year. That straight math is 81,000. And so the present value of that, how

much money it would take today to provide that then from age 21 then for an additional 60 years starting at 21 which would be -- it would be 82,114. And at .005, it would be 82,867. So I've done this with respect to all of these categories that are related -- that are medically related. She will explain each individual and why this child needs it.

At the bottom then --

MR. BOTTARO: If you'll scroll up, please.

Q. Go ahead.

A. At the bottom then if you notice she has a couple of costs in there that she doesn't have any costs involved in it, so I can't put anything in like for the MRI.

But when I total those up then, the medically related, then without any present value, that cost over her lifetime would be 1,815,949. And at the .03 percent, it would be 1,833,810. And at .05 percent, it would be 1,845,860.

Now, the next category of items are those that are more inflation related. For example, the wheelchair and the wheelchair back and the maintenance.

Q. I think it's entitled equipment and supplies by Ms. Pollard; is that right?

A. That is correct.

Q. Okay. So this is the next category of life care plan damages or charges.

A. Now, what happens here then is I have two different

discount rates here. I have the relationship then between inflation and interest rates. And the interest rates have been over a longer period of time, over 50 years, 2.1 percent greater, the interest rates have been, than the cost of living. So, again, I'm assuming these costs are going to go up. But the monies to be provided for these will be invested in short-term government's. Over a shorter period of time over the last 20 years then, that discount rate is 2.06.

So, for example, then you can see over time these costs' present value then will be reduced. For example, on the wheelchair beginning at 5, a manual one for 75 years, an annual cost is 1,500. Now, what she'll have is she'll have a cost -- and I forget the exact number but probably something like $7,500, and then it's going to be -- it can be used for five years. So I find an annual cost. And in that particular case then the annual cost then would be 1,500. That total would be 112,500. The present value of that then over that 75 years period of time would be 56,399. And at 2.06 percent, it would be 57,037. So --

Q. Now if we could go I think to the next page, page 7, that's the rest of the equipment and supplies that Miss Pollard has called for in your calculations; is that correct?

A. That is correct.

Q. Let's go --

MR. BOTTARO: Scroll -- keep scrolling -- yes, keep

going up, please.
Q. All right. There we go.
A. Now, the totals then of those items at the 2.1 percent and the 2.06 percent would be then the one million -- the straight multiplication would be 1,931,431, but at a discount rate of 2.10, it would be 961 -- 976,131. And at 2.06, it would be then 987,015.
Q. Then I see you have totals. And are those from the two categories of the medical care and treatment and then the equipment and supplies, and that's the totals we see in the box with 3,747,380; is that correct?
A. That is correct. That's simply the totals of those two different categories.
Q. And then explain the two different present value just amounts so the jury can see them, please.
A. The -- her recommendation, Lisa Pollard's, was for -- to have a barrier-free home, and I believe she used a 200 -- 185,000 to something like 219. I used the 185,000. But they're paying rent right now of so much a month. So I found the present value of that then and -- because that's what her cost would be, subtracted that from the 185,000, and it would be approximately $31,000 over and above what her current cost of the rent that they are currently paying to have a barrier-free home. So that's the 31,100. And that's today. That doesn't have anything to do with present value.

Then in her report I was given two options, option 1 and option 2. And option 1 then is respite service in her home.
Q. And what does that mean, do you understand, respite service?
A. I have heard term. It is when the -- she's going to have to have care and the def -- I'll have the exact definition of it. This would be where she has 18 hours per month at $41 per hour, and then --
Q. 18 hours per month of what? Or is it per month or week or --
A. It is per month.
Q. Of what?
A. That would be for weekends and things like that where they're going to have to bring in additional care.
Q. Someone from outside the home.
A. Somebody from the outside, that is correct.
Q. And tell us what those figures are then, what they show.
A. Okay. And those two numbers basically showed she had two separate costs for those, one being 23,616, the other being 115,128. Those totaled then 138,744.
Now, the discount rate that I've used there -- those are all wage related. So I've used the discount rate that I used initially, the 1.82 percent and the 1.49 percent so that the present value then -- so the straight multiplication of 75 years at 138,744 would be then 10,405,800.

Then the present value of that at the 1.82 percent would be 5,109,401 plus the costs from above of 2,840,941. So the total then of option 1 using a discount rate representing relationships of 50 years would be 7,950,343 and at the 20-year relationships between the interest rates and the other factors would be 8,033,117.

Q. So that would be for part-time help coming in to give some relief to the family in caring for Jeanine Kunkel.

A. That is correct.

Q. All right.

A. The other then would be 24-hour care 7 days a week.

Q. In the home.

A. In the home.

Q. And talk about those numbers, please, for the jury.

A. And that would be then -- the total cost of that would be 359,160, and that again --

Q. Per year.

A. Per year. That would be for 75 years. The straight multiplication of that would be twenty-six million nine thirty-seven. And then at the discount rate of 1.82 percent, the present value of that would be 13,226,465, plus the above losses, 2,840,941, would give me 16,067,406.

And using the same process then using a discount rate for the home healthcare of a -- of 1.49 percent, that would be 13,381,369, plus the above losses. The economic loss there or

the cost of the present value of the healthcare plan would be 16,245,245.

Q. Does that complete your opinions related to the -- your projections for both the loss of future earning capacity and the life care plan as prepared by Lisa Pollard?

A. Yes.

MR. BOTTARO: And at this time, Your Honor, I'd move to admit Exhibit 169, the report of Dr. Sherman.

* * * *

(Exhibit 169 was offered.)

* * * *

MR. GRAY: Your Honor, we do continue our objection made prior to the court --

THE COURT: Sustained.

MR. BOTTARO: No further questions.

MR. GRAY: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. GRAY:

Q. Dr. Sherman, good morning again or good afternoon again. You and I have met before?

A. Yes, we have.

Q. I have asked you to represent me or my clients, and I've also cross-examined you before.

A. Correct.

Q. All right. And, sir, I think it's fair to say that as you

sit here today you are someone who is an economist or someone who's very knowledgeable in finance.
A. That is correct.
Q. All right. And it would be also fair to say that you're not here today to give any medical opinions about the -- how this child developed bacterial meningitis.
A. Correct.
Q. Or you're not here to give any opinions as to the child's long-term medical program or her medical care; is that correct?
A. Correct.
Q. Actually part of what you've been asked to do here today is to make calculations based upon facts or numbers or assumptions provided to you by someone else; isn't that right?
A. With respect to the life care plan, that is correct. My numbers I generated myself with respect to the loss of the earning capacity.
Q. Sure. And the numbers you provided for them, of course, you have to be told the age of the child exactly.
A. That's correct.
Q. All right. And is it clear for me and for the jury that you don't go out and do an independent investigation as to the costs of any particular medicines or the costs of any particular medical treatment?
A. Correct.
Q. It's certainly just not your role, is it?

A. Correct.
Q. Now, I'm also correct, aren't I, that you can do calculations based upon the numbers and the facts, the assumptions that you are given, and those calculations may be completely accurate?
A. Those assumptions may be completely accurate? That's correct.
Q. Right. No, no, no, your calculations would be completely accurate. In other words, you're given certain information.
A. Yes.
Q. You do calculations, and you hope those calculations are accurate.
A. I did -- that was given to me, hopefully I did the math correct.
Q. That's right. And because you don't go and investigate those assumptions or those numbers or those facts, you can do correct mathematical calculations, but if the facts or the numbers of the assumptions are incorrect through no fault of your own, you can have correct mathematical calculations but maybe not accurate presentation of the facts.
A. Well, I view my role as methodology, and so consequently, if -- let's assume when Lisa Pollard comes and there's a cost that's established that it was $200 a year less, the methodology is here. These people are the ones who are going to make the decision, and they obviously can do the calculation then.

Q. Correct.
A. Because I've given them the methodology.
Q. And that's really what you're here about to do today is -- for the life care plan is to give us the methodology, not necessarily -- you can't guarantee for certain that the number is accurate because you don't know and couldn't investigate the accuracy of the information you were given.
MR. BOTTARO: Your Honor, I'm going to object as that being a misstatement. I think the witness has testified his numbers are accurate. I think the question is something different than what he's trying to get at if you understand. I think he's talking more about questioning the underlying assumptions by Miss Pollard, but I think the witness has testified his calculations are correct.
THE COURT: That probably set the record for a speaking objection which is overruled -- which is overruled.
THE WITNESS: Oh, okay.
THE COURT: So you want -- nobody's going to remember now.
THE WITNESS: I think he misspoke. Ask the question again then because I think the first part wasn't quite right.
THE COURT: Well, just a second.
THE WITNESS: Oh, sorry. What --
THE COURT: Just a second. I don't know what other courts you've been in, but in this court the witnesses don't get

to ask the questions of the lawyers, and I suspect that's been pretty consistent in your career. So we're going to leave it up to the lawyers to ask the questions of the witnesses, and you can answer the question that gets asked.

THE WITNESS: Okay. Thank you, Your Honor.

THE COURT: And if you want to go to law school, then you can become a lawyer and ask witnesses questions.

BY MR. GRAY:

Q. For example, Dr. Sherman, one of the assumptions or one of the things you've used in your life care plan is you've calculated that she has a life expectancy of 75.95 years. Did I read that correctly from your statement?

A. I looked at the tables.

Q. Okay. Let's talk about that.

A. And the tables say 75.95 I think. I used 75 as her life expectancy.

Q. And the table you looked at to get that 75 was called the standard ordinary mortality table?

A. Correct.

Q. Okay. And do I understand correctly that that's an actuarial table; correct?

A. That's correct.

Q. Would you tell the jury what an actuarial table is, please?

A. Basically the life insurance people use it to determine --

Q. Could you move up to the microphone, please?

A. Oh -- to determine life expectancy of individuals by different ages to determine -- one of the things that they determine is what the life should be to determine costs for insurance.
Q. Sure. And those are basically averages, aren't they?
A. Correct.
Q. Okay. For example, a 53 -- based on those tables that you used, a 53-year-old man who has just finished a triathlon, just been given a clean bill of health from his doctor would have the same life expectancy under that table as a 53-year-old man who has terminal pancreatic cancer; isn't that correct?
A. Would the tables show that?
Q. Yes.
A. That is correct.
Q. Now, you'd agree with me I hope that if this child's life expectancy was 21 years instead of 75 years that the present value of the life care plan would be significantly lower, wouldn't it?
A. It certainly would.
Q. And wouldn't it also be true that if the child's life expectancy was 21 years instead of 75 years that your calculations for potential loss of earning capacity would be substantially lower?
A. Correct.
Q. Just maybe on a minor note, but you had on the screen some

of the different categories of things that need to be paid for suggested to you by Lisa Pollard. Were you reading from that?
A. Correct, yes.
Q. And one of those things -- excuse me, sir. But it appeared to me that some of those were one-time-only expenses.
A. Correct.
Q. And you have done this projected life care plan several times, haven't you, during the course of this litigation?
A. I think I did an original one and then I made an adjustment or two again.
Q. Sure.
A. So that is correct.
Q. And since that time you did the initial one, if those services have already been paid for, those should be included in past medical expenses rather than future; wouldn't you agree with me?
A. I think you'll have to ask Lisa Pollard that.
Q. Okay.
A. That's her decision. I'm just reading what she is saying what will be necessary and whether -- you know, there could be something for one year. I just interpreted what she did, and if she wants to then -- when you ask her that, that can be checked off if it's already been done. I don't have any problem with that.
Q. Sure. And that would decrease your amounts by that amount,

wouldn't it?
A. That's correct.
Q. All right. And also if when I talk to Lisa Pollard she would say, for example, that there will be no expense for an optometrist from the age of 29 to 80 and you have such a cost of about $2,100 on your plan, would you agree with me your plan is overstated if it's based on what Lisa Pollard says?
A. That is correct. What you do then, the numbers are all there. They would simply subtract that line out. The methodology is there for these people to make a decision.
Q. And we'll go back to Lisa Pollard and find out how good the information was that you were given; correct?
A. Correct.
MR. GRAY: Very good. Thank you, sir.
THE COURT: Any redirect?
MR. BOTTARO: I don't believe so, Your Honor.
THE COURT: Okay. Member -- just a second. Members of the jury, do we have any questions for this witness? Okay. Doesn't look like it.
You're free to go. Thank you.
THE WITNESS: Thank you, Your Honor.
THE COURT: You all can take a stretch break if you like.
Dr. Jason, you can just return to the witness box, and whenever Miss Ghezzi is ready, she'll start in again on

cross-examination.

MS. GHEZZI: Do you need some water?

DR. JASON: I had some. Thank you.

JANINE JASON, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CONTINUED CROSS-EXAMINATION

BY MS. GHEZZI:

Q. Okay. Dr. Jason, you're not aware of any sealed can or package of Abbott's powdered infant formula on the U.S. market that tested positive for E. sak ever, are you?

A. That's not something I've looked at in detail.

Q. Okay. So you're not aware of it.

A. No.

Q. You're not aware of any time where it's ever tested positive in a sealed can; right?

A. I don't know one way or the other.

Q. Okay. And you're aware that Abbott has never had a recall of any powdered infant formula on the United States market ever for E. sakazakii.

A. For E. sak, no.

Q. Right. Now, in 2000 -- December of 2011 you wrote a letter to the Food and Drug Administration because of your work with E. sak in these cases; right?

A. No, because of the findings in my manuscript.

Q. Okay. But that was at the same time that you're working in these legal cases; right?

A. Same time period.
Q. Okay. And -- and you told the FDA in your letter your opinion that E. sak is unevenly distributed in implicated powdered infant formula products; right?
A. Correct.
Q. And you told the FDA your opinion that manufacturers' finished product testing should be changed; correct?
A. That something should be done about it.
Q. Okay. And you told the FDA your belief that powdered infant formula warning labels should be changed; correct?
A. Correct.
Q. Okay. And these are the same opinions that you're giving in this case; right?
A. Correct.
Q. And you received a response from the FDA, in fact, the director of infant formula and medical foods staff at the FDA's Center For Food Safety and Applied Nutrition on March 1, 2012; correct?
A. Correct.
Q. And that gentleman's name is Benson Silverman; correct?
A. Correct.
Q. And he told you in that letter that the FD -- that since 2002 the FDA has participated in the development of the World Health Organization reports on microbiological standards for C. sakazakii in powdered infant formula, and together with CDC,

the agency has investigated all cases of C. sakazakii infections reported in infants; correct?
A. I would have to look at the letter, but that sounds reasonable.
Q. Let's look at the letter.
MS. GHEZZI: Excuse me one moment, Your Honor.
Q. Okay. It goes -- so it says -- okay. So it says there since that time -- and it's referring to its web page on 2002 -- in 2002. Do you see where it says that, that I just read?
A. I'm not sure what you're saying. They're talking about the outbreak, and they're talking about the web page both.
Q. It says since that time FDA has participated in the development of the World Health Organization's reports on microbiological standards for C. sak in powdered infant formula, and together with CDC the agency has investigated all cases of C. sakazakii infections reported in infants. Do you see that?
A. I do, yes.
Q. Okay. And then they also told you if you follow -- on the bottom paragraph right there it says FDA -- this right here starting here, FDA conducts careful examinations of manufacturers' records and facilities as part of all investigations of reported C. sakazakii cases as well as for investigations of any other problems with infant formula products, and inspection of all infant formula manufacturing facilities is an FDA priority. And then he goes on to say each

plant that manufactures infant formula for distribution or sale in the United States is subject to inspections when production begins and on a yearly basis thereafter and whenever an inspection is needed because of a problem with a product. Microbiological testing records must be made available to FDA investigators for their review during these inspections. Do you see that?

A. Yes.

Q. Okay. And if you turn -- -- and in the second paragraph -- the second paragraph, he tells you right here we are aware of the findings of Jongenburger; correct?

A. Yes.

Q. And that was an article that you relied on in your examination today by Mr. Rathke, one of the things; right?

A. Correct.

Q. And he points out that the sensitivity of C. sak testing is slightly increased by stratified sampling, but the amount of material tested has the greatest impact. And Jongenburger in the discussion about the random sampling results point out that random sampling -- with random sampling the probability of finding a contaminated sample increases with the number of samples tested, all of this. And then he says FDA has tested and continues to test large amounts of product -- of powdered infant formula from unopened cans of lots implicated in C. sakazakii cases when available. Do you see that?

A. I see that.
Q. Okay. And then if you go to the end of that paragraph, he tells you the results of case investigations have not indicated that any particular company or product is implicated in C. sakazakii cases. It is unknown how the infant formula becomes contaminated with C. sakazakii, but the evidence from investigation thus far is consistent with packaged powdered infant formula being negative for C. sakazakii when it leaves the manufacturing plant. He told you that in March of 2012; right?
A. He said nothing here that's inconsistent with what I've said. They have negative tests. That's all they have. This is what's called a controlled correspondence, and it's what I would have expected to have gotten back from the FDA.
Q. Because you don't trust the FDA to keep the food supply for infants in the United States safe.
A. No. You're saying that. I've done controlled correspondences, and it's written like an elephant. It has a lot of different pieces, and I definitely touched a nerve, and it's a very polite response saying don't worry, we're doing our job, and that's exactly what I expected to get.
Q. Okay. Now, after you wrote the letter, the FDA did not ask infant -- powdered infant formula manufacturers to change the labeling, did it?
A. I have no idea.

Q. You haven't looked at a -- you haven't looked at a label on a powdered infant formula product since March of 2012?
A. Well, that's a different question. I have no idea what the FDA has said or interacted with in terms of these comp -- the formula companies.
Q. Okay. That's a fair point. Let me ask you this. Have the labels changed? Do you know whether or not the label that Mr. Rathke showed you today has changed?
A. At least for some things that I have looked at there has been a change, yes.
Q. Have there been any change in terms of putting on a label, anything on a label, that talks about a neonate?
A. I'm not sure what you're asking.
Q. Have you seen any label that has "don't feed this to a neonate"?
A. Nothing that I've seen, no.
Q. And have you seen anything that says you should say that there could be bacteria in this product?
A. We're talking on the label?
Q. Yes.
A. Have you -- so could you rephrase your question?
Q. Have you seen any label since you wrote your letter and Mr. Silverman responded in March of 2012 on a label that -- for powdered infant formula that says this can contain bacteria that can cause meningitis or --

A. Not that I've seen, no.
Q. Okay. Now, you can't identify any of the three feedings given to Jeanine Kunkel that contained E. sak, can you?
A. Could you phrase that a different way?
Q. Well, she had three feedings.
A. Yes.
Q. 9:00, midnight, and 4 a.m. And you can't identify any one of those that you can say contained E. sak.
A. I can say that the most likely would have been the first feeding. But no, I can't by definition.
Q. Okay. So it's your opinion that the first feeding is the most likely.
A. Correct.
Q. And the reason you say that has actually nothing to do with the feeding. It has to do with the fact that in order for you to say that -- or come to the conclusion that the powdered infant formula had E. sak in it, you have to have a certain number of hours between when she was fed and when her symptoms appeared; right?
A. Well, I don't know that it's hours. You need some period of time. Clearly it could be as few as six hours according to some of the research. But the longer time period, the more growth you would have. So it could be the others too. All I'm doing is guessing which one it would be.
Q. Right. That's all you're doing is guessing; right?

A. In terms of which feeding, yes.
Q. Right. And, in fact, you haven't even ventured a guess that it's the first. You're saying if you were to guess, it would be the first.
A. Correct.
Q. Okay. And we'll talk about the six hours. But just real quickly, there's not a single scientific article, study, manuscript, report, anything of the sort, that says that a baby can develop meningitis in six hours after eating powdered infant formula, is there?
A. Within six hours?
Q. Right.
A. No. If you look at some of the sporadic cases, conceivably those could have happened in a period between 7 and 24 hours.
Q. We'll talk about that la -- oh, so not 6 but 7.
A. You're just asking me what data there are, and I'm telling you in terms of what they have in CDC documents there is one possible case where there was a seven-hour interval. I'm not saying that's a magic time period. You just asked if there was any data.
Q. What CDC case is that?
A. It was a California case that is not included in my article, but as I say, your question was is there any data whatsoever.
Q. And it's not included in your article because you couldn't

tell it came from powdered infant formula?
A. It's an infant with -- rather it was a child with -- I guess an infant with an underlying disorder.
Q. Right. So when you were picking out your data to put in your manuscript so that you could come up with your number of 90 percent of cases are connected to powdered infant formula, you left out every infant who had an underlying medical condition; right?
A. My goal was not to come up with some number of powdered infant formula. I was surprised at that finding. That's why I wrote the FDA.
Q. Okay. My --
A. I did it because I wanted to look at serious cases, ones least likely to be missed by reporting. And I wanted cases that involved significant disease. Look at what you told me, how few cases there were. And you're not the first person to say it's rare. So what? Well, to me it's so what if it causes meningitis and serious illness.
Q. Okay.
A. So those are the ones I chose to look at. This is an opportunistic infection. So if it happens you would expect it to happen in an immunocompromised patient. So my question that I was addressing was I want to see the characteristics and changes in characteristics of infants with -- or children. I didn't -- you know, it turned out to be infants, but it was

basically any pediatric case with no reported underlying immune defect, presumably previous normal infants who then went on to get invasive disease.

Q. So my -- the answer --

A. The powdered infant formula shook out. It was not something I came in there looking for.

Q. So the answer to -- so the answer to my question is that you didn't consider in your study or your analysis any infant who had invasive cronobacter or E. sakazakii illness if they had an underlying medical condition. I'm not castigating -- and I'm not asking you about --

A. The first --

Q. Excuse me. And I'm not asking you about your motives. I'm asking you whether or not you included them. You did not include them; correct?

A. No, that's not quite correct, and actually you did imply my motives were not appropriate. But I did include them. The first paragraph was actually looking at the number of those cases and then just describing them and then explaining that I now wanted to move on to the group I just described to you.

Q. I'm going to quote you from your article. Children were not included in these analysis if their infections were noninvasive or they had underlying birth defects, medical conditions, or signs of immunodeficiency. Was that a true statement when you wrote it in 2012?

A. That in the analyses if you look at the first page -- paragraph of my results, I then give numbers for how many I looked at that had underlying deficiencies.
Q. You mean in your supplement --
A. So I defined my study population.
Q. Excuse me, Dr. Jason. Are you talking about in your supplement when you --
A. No. If you look at the first page --
Q. My only question to you is was this true when you wrote it at the time?
A. Was what true?
Q. The statement I just read to you that children were not included in your analyses if their infections were noninvasive or they had underlying birth defects, medical conditions, or signs of immunodeficiency. Was that correct when you wrote it in 2012?
A. They were not in the analysis of --
Q. Okay. That's all I asked. Thank you.
Now, you talked about ST types, sequence types, of a certain kind of E. sak called cronobacter sakazakii; right?
A. Correct.
Q. Okay.
A. Correct.
Q. Now, Jeanine Kunkel's E. sakazakii isolate was never typed. In other words, nobody analyzed it to get what the sequence type

was in this case ever; correct?
A. That was not available, and no, it was not.
Q. Okay. And, in fact, no one analyzed the E. sakazakii isolate that came from Jeanine Kunkel to see, in fact, if it was cronobacter sakazakii or cronobacter something else; correct? No one did that analysis.
A. I don't know that one way or the other.
Q. Okay. You've never seen it or you'd tell me about it; right?
A. Well, you know what? You should ask the microbiologist that. It was typed as C. sakazakii, and they could give a better answer to that.
Q. Okay. Are you saying that her medical records said that she had E. sakazakii -- or C. sakazakii meningitis as opposed to E. sakazakii meningitis?
A. No, n -- oh, I see what you're saying. No, it was -- yes, it was E. sak.
Q. Okay.
A. So it was pre-cronobacter. I see exactly what you're saying. And no, I don't know whether it's ever been typed with the newer number.
Q. Right. So you don't know as you sit here today whether she had C. sakazakii or ST4 sakazakii.
A. I do not, no.
Q. Okay. And, in fact, you are aware that there are a lot of

different sequence types or STs that have been associated with illness in infants; correct?
A. Not invasive illness. There is one other type that cause serious illness in, I believe, one case.
Q. Okay. Well, you think that -- I mean, we all think -- I mean, meningitis is a serious illness; right?
A. Correct.
Q. Okay. And you're aware that ST type 1 --
A. That is the one I was talking about.
Q. -- ST type 3, and ST type 4 have all been reported in cases of infant meningitis; right?
A. ST type 3 I'm not aware of. ST type 1, I know that case.
Q. All right.
A. I'd have to look at the ST3.
Q. And, in fact, there are at least six others that have been reported as causing illness in infants and they are ST -- well, the 1, 3, 4 and then 12, 13, and 31; right?
A. If those are in the ST4 family -- are those the ones you're looking at? There are some that are in the ST4 family, but they're a different type.
Q. No, these are different ST types. It's ST12, 13, and 31 in the literature, specifically Forsythe's?
A. Which paper was that?
Q. Joseph and Forsythe.
A. Joseph and Forsythe?

Q. Right. Are you aware of that?
A. Joseph and Forsythe showed that by far the predominant type in infantile meningitis -- and I'm not saying a hundred percent -- but by far the predominant type was ST4.
Q. In fact, it was a little more than just 50 percent; right? Actually it was 44 percent. The Joseph and --
A. It's 20 out of 41. Is that the one you're talking about?
Q. It was 20 out of 41.
A. Yes, and the rest are just a smattering here and there. And that doesn't just include infants. That includes all isolates.
Q. No, I'm sorry. It wasn't 20 out of 41. It was 10 out of 18. It was 10 out of 18 which is 44 percent.
A. Let me -- actually I've got that table. Let's get a look at that.
Q. It's not in your table. You didn't put it in your table.
THE COURT: 10 out of 18 is not 44 percent.
MS. GHEZZI: No, no. I'm sorry, Your Honor. It's 44 percent is the opposite. It is that 44 percent was not ST4.
Q. If you're looking at 10 out of 18 neonates -- or sorry, neonates where it was ST4, that means 8 were not ST4, and that is 44 percent of the 18 were not ST4.
A. Yes, but we're also talking about all infections and not just the invasive infections, and I did actually have a slide for that. I didn't show it.

Q. Dr. Jason, you're relying --
A. Can you --
Q. You're relying on -- I'm not -- you're relying on this Forsythe article for your ST --
A. No, I'm relying on the Joseph article --
Q. That's this article, Joseph and Forsythe.
A. The -- what is his name? The preceding article that did the 21 out of 40, the FDA results, and the CDC results that have come out recently.
Q. Okay. Where somebody was -- but -- okay. But I'm asking you now about Joseph and Forsythe.
A. Okay. That is not the sole basis of my making the statements.
Q. No, but Joseph and Forsythe was on your slide, and what you were talking about there was --
A. I don't think I had a slide on Joseph and Forsythe.
THE COURT: Excuse me, doctor. We're having a problem here, and it's that you're each interrupting each other. So, Dr. Jason, you need to wait until Miss Ghezzi has asked her question. And you need to allow her to finish her answer unless you're interposing an objection.
MS. GHEZZI: Okay. Thank you, Your Honor.
THE COURT: Okay? Thanks.
MS. GHEZZI: Thank you, Your Honor.
BY MS. GHEZZI:

Q. Are you aware that ST1 and ST4 have been isolated from a variety of sources including children and adults, chocolate, washing brushes, wounds, and elsewhere in the environment?
A. On rare occasion there have been isolations, but if you show me those data, we can look at them.
Q. And are you aware that the source for that is the Joseph and Forsythe article?
A. As I say, if you want, let's look at that table.
Q. We don't have to look at it. I'm just asking you are you aware that that's where it comes from?
A. I am aware of that.
Q. Okay.
A. And I think you need to look at their own conclusions and see that they conclude what they conclude about ST4 and invasive infection in infants.

MS. GHEZZI: Okay. Your Honor, I don't believe that a question was pending, so I'm going to move to strike it.

THE COURT: Sustained. The last portion of the witness's answer is stricken. And as jurors, you're advised to disregard the last portion of the answer.

BY MS. GHEZZI:
Q. Now, Dr. Jason, Mr. Rathke asked you about your review article and the fact that when you sent it in people review what you've done and then you have a chance to propose some of the reviewers, who's going to look. Doesn't mean they're going to

let you have the reviewer that you chose, but you get to suggest some reviewers that you would like to review your article to see whether or not it can be published in a peer review manner; correct?

A. That, and people you would prefer not to have, yes.

Q. I'm sorry.

A. That, and reviewers you would prefer not to have.

Q. Right. The reviewers you would prefer not to have. And so in October -- on October 18 of 2012, you write -- you wrote an e-mail to Jim Farmer. We talked about him. He's the one who found the E. sak in his dog's water bowl. And you said, "Do you have any thoughts on whom else I might suggest as a reviewer?" You asked him to be a reviewer; right?

A. Correct. Well, no, that's not quite right. I asked if I could put his name on the list of people that I suggest.

Q. Okay. Fair enough. And then you said, "Equally important, do you have any advice on whom I request they not use as a reviewer?" And one of them listed was Forsythe, Mr. Forsythe.

A. Dr. Forsythe.

Q. Dr. Forsythe; right?

A. Correct.

Q. And he's the doctor who -- he's the scientist, rather, who wrote the new articles on the sequence types; right?

A. Correct. But I'd have to say I'd ask for him if I knew what I knew now, now that he's done --

THE COURT: There's no question pending, doctor.

THE WITNESS: Sorry.

MS. GHEZZI: Thank you, Your Honor.

Q. Now, I want to move over to a question about Jeanine Kunkel's infection, okay, some questions. You would agree with me that one of the symptoms of early onset meningitis is irritability, crying; correct?

A. In association with other symptoms, yes.

Q. Okay. And you gave a deposition in the case; right? You've referred to the deposition a few times. And in your deposition you said that the baby's crying at nine o'clock at night was due to colic; right?

A. What will become colic --

THE COURT: That's an improper question. You can't ask her what she said in the deposition.

MS. GHEZZI: Okay.

THE COURT: You can use it to impeach her if she says something different.

MS. GHEZZI: Okay. Thank you, Your Honor.

THE COURT: What she said in a deposition is hearsay.

BY MS. GHEZZI:

Q. Your opinion in the case and your report was that the baby had colic; right?

A. Well, it's just semantic. Colic is not officially diagnosed till about three weeks of age, but that's because you

have to have symptoms of it for a certain time period to meet the definition.
Q. Right.
A. So with that caveat, I would say yes.
Q. You would say yes, that it --
A. That it was basically an irritable infant.
Q. Right.
A. That could be eventually diagnosed as colic.
Q. Right. But she didn't have colic then. It wasn't colic.
A. Only semantically because it hasn't been three weeks of doing the same thing again.
Q. Well, in the medical records that you reviewed for Jeanine Kunkel, is there any mention ever of colic?
A. By then she couldn't have shown colic. She had massive meningitis. You can't -- you can't --
Q. In the first three weeks --
A. You can't diagnose colic when an infant is suffering from meningitis.
Q. In the first three weeks of her life --
A. That's absurd.
Q. -- did she have colic?
A. Colic is defined in a healthy infant who is irritable, especially in the evening, and has been so for three weeks.
Q. Right.
A. By then she was not a healthy infant. Her brain was

riddled with holes. She had reason to be irritable because she had meningitis. You can't diagnose colic in that setting.

Q. Dr. Jason, Jeanine Kunkel was taking food orally by mouth when she was three weeks old, right, three weeks, four weeks old. She was taking food by mouth; right? You saw that in the medical records.

A. Yes, she was.

Q. Okay. You would agree with me, right, that if an infant is first fed powdered infant formula after it begins showing -- he or she begins showing symptoms of meningitis that the powdered infant formula cannot be the source of that illness; right?

A. Yes.

Q. Okay. And so the timing of when Jeanine Kunkel's symptoms began is -- first began to appear is crucial to your being able to say that Abbott's formula was the source of the bacteria in this case; right?

A. Correct.

Q. Okay. And the first feeding we all agree was at 9 p.m. on April 23, 2008; right?

A. Yes.

Q. And when you were forming your opinions in this case, you looked at her medical records, and you looked at CDC records and the investigation records; right?

A. Yes.

Q. And the Nebraska Department of Health and Human Services

records; correct?
A. Correct.
Q. And you read the Megan Surber deposition, the mom.
A. Yes.
Q. Right? And that was taken July 5 of 2012 which is more than 4 years after the baby was born; right?
A. Yes.
Q. And you read portions of Jeanine Kunkel's grandmother's deposition as well; correct?
A. Correct.
Q. And in those depositions you learned that at nine o'clock, around nine o'clock, Janine Jason called her mother --
A. I'm Janine Jason.
Q. I'm sorry. I'm tired. Megan Surber called her mother, the grandmother of Jeanine Kunkel, and said the baby is crying and crying and she was nervous about it and that's why she called her own mother about it at 9 p.m. on the evening of April 23, 2008; right?
A. Correct.
Q. Okay. And her next feeding was at midnight; right?
A. Correct.
Q. And her next feeding was at 4 in the morning.
A. Correct.
Q. And at 4 in the morning Miss Surber stated that she was getting -- the baby was by then getting really, really

off-the-wall whiney; right?
A. My understanding was that it was not till later in the morning that that was the case.
Q. Okay. But you read her deposition where she testified that and then four o'clock is when she started getting really, really off-the-wall whiney.
A. It's my understanding that her corrected testimony indicated that it was later in the morning.
Q. And her corrected testimony was done two months after the initial deposition was taken in this case when she testified under oath; right?
A. I would have to go back and look.
Q. Okay. And then -- and then it was at 9 a.m. in the morning when she started getting really, really finicky, and she wouldn't eat and so she didn't take a feeding -- she didn't take her 8:30 a.m. or 9 a.m. feeding; right?
A. She did not take that feeding at either time, yes.
Q. Right. She didn't take that feeding. So the last feeding that she had was 4 a.m. in the morning; right?
A. Correct.
Q. Okay. And the baby did not eat anything else from 4 a.m. in the morning until at least 6:15 the next day, p.m., when she was admitted to the emergency room at St. Luke's Hospital; right?
A. I wasn't clear whether she got anything into her, but

clearly she was not eating much.
Q. Well, there's absolutely nothing in the record that indicates that she fed this baby anything after 4 a.m. in the morning; correct?
A. She certainly attempted to feed this baby.
Q. She attempted to feed her, right, in the morning, 8:30 to 9 a.m.
A. No, there is no way a mother has not attempted to feed her baby through the day.
Q. Well, she may attempt to feed the baby, but the baby didn't eat.
A. And as I say, I have no idea. Clearly the baby didn't eat much, but she did try, and I have no idea how much she got into her.
Q. Okay. And now, but you would -- but you would agree that -- well, let me show you a record. Let me show you Exhibit t -- 1000G, please. And we've already recognized I'm a terrible artist, so I'm going to try and do this the right way, but bear with me here. So this is Exhibit -- and if you look at the top of that exhibit, we see the admit date; right?
A. Correct.
Q. And that's April 24, 2008; correct?
A. Correct. Now, is this the discharge or admit? Can you pull that down a little bit?
Q. Yeah, sure.

A. Okay. All righty.
Q. Okay? And this is the doctor that Megan Surber called, Dr. Susan Caldwell; right?
A. Correct.
Q. And so she says this is a ten-day-old infant who was brought in, mom, presumably by mom, because of fever and irritability. Mom states since last night she has been fussier than normal. You see this?
A. I do, yes.
Q. Okay. And then this morning her temperature was 99.1 and then this afternoon her temperature went up to -- this is terrible. I'm going to undo that. Her temperature went up to 100.7 degrees rectally. She has been fussy throughout the day, and she has not been eating well as normal; right?
A. I agree that from the mother's deposition she was fussy throughout the day and that 100.7 was her first temperature that was abnormal.
Q. Well, her -- but she has a temperature in the morning of 99.1; right?
A. That's a normal temperature.
Q. Not for a newborn it isn't, is it, for a small baby? They have lower body temperature than normal people?
A. No, no. In fact, a low body temperature is a sign that something's wrong.
Q. Right. So -- well, not in a newborn it isn't, is it?

A. Yes, it is.
Q. Okay. So if an infect -- if a pediatric infectious disease doctor who's worked with these kinds of infants for the last 35 years disagrees with that statement, you would agree --
A. I am also an infectious disease doctor who I'd have to count it but unfortunately probably more than 35 years have worked with these infants, and temperature instability is a sign of severe infection, and that includes a very low temperature as well as an elevated temperature.
Q. Yeah, but -- that's fine. I didn't say very low temperature. I'm saying that a baby with -- a baby of Jeanine Kunkel's age and weight is going to have a lower body temperature than 98.6; right?
A. That -- the range will go down lower, but she will not necessarily be lower than that, no.
Q. Okay. Well, we have a disagreement there but. . .

Okay. So --

MR. RATHKE: Move to strike.

Q. 10,001B. But -- and -- but you're not disagreeing with Dr. Caldwell that Mom states since last night she's been fussier than normal; right?
A. I am not disagreeing that the mother said in the evening that Jeanine was fussy. Her mother says that she did not hear Jeanine crying in the background during that phone call and that the mother describes that evening fussiness as normal fussiness,

and she already has one child, so she knows what fussiness is. She describes the next day as being very, very different. So the details -- the devil is in the details.

Q. Yeah, exactly. And so when she called her mother at 9 p.m. or around 9 p.m. on the evening of April 23, 2008, and said Jeanine is crying and crying and she was worried about her, you would describe that as normal?

A. I think that would be very normal for a cranky child.

Q. No, no, no, normal for a mother to call her mother.

A. Oh, yes, my goodness.

Q. Okay. Okay. Do you remember the -- I'm going to put Exhibit 1001B up. This is Children's Hospital of Omaha discharge summary. Okay. Can you see that, Dr. Jason?

A. Yes, yes.

Q. Okay. Do you see that highlighted portion right there?

A. Yes.

Q. And that says briefly the baby was at the time of admission -- now, this is -- this is -- she spent two days in St. Luke's, and then on April 26 she went to the Children's Hospital in Omaha; right?

A. Correct.

Q. The patient was at the time of admission a 12-day-old infant, product of a term twin pregnancy delivered by Cesarean section with an unremarkable past medical history. She began not eating well in the 24 hours prior to her admission. She

then developed a low grade fever to 100.7 rectally. Okay? Now, she was admitted to St. Luke's at 6:15 the evening of April 24, 2008; correct?

A. Correct.

Q. Okay. And so when Dr. Susan Caldwell writes on this that she began not eating well in the 24 hours prior to her admission, that would suggest and that would mean that Jeanine had not been eating well since 6:15 on the evening of April 23, 2008; correct?

MR. RATHKE: Your Honor, I have to object. That is a misstatement of fact. That wasn't by -- well . . .

THE COURT: You know, without your microphone on, I couldn't really hear what you said.

MS. GHEZZI: Oh, I'm sorry. It's Dr. Snow. I apologize, Your Honor.

THE COURT: Does that take care of whatever your objection was that I didn't hear?

MR. RATHKE: (Nodded head.)

THE COURT: Okay. Why don't we give everybody a stretch break.

Thank you. Please be seated.

BY MS. GHEZZI:

Q. Okay. Dr. Jason, I'm going to put up Exhibit 1001A. I went a little out of order, so I apologize. I think -- so this is date of admission. This is the admission to the Children's

Hospital in Omaha on April --
A. Did you have any question about the last one?
Q. I did ask you a question.
A. And what was that?
Q. We're going to this -- this is Exhibit 1001A. Okay? And can you see the date of admission up there right here?
A. Yes.
Q. Okay. And then what this document says is this is a 12-day-old infant who was most recently admitted to St. Luke's Hospital at Sioux City, Iowa, for fever and irritability 2 days ago which would have been April 24; correct?
A. Correct.
Q. The child was described, had been fussy all the night prior to admission and on the morning of admission had a temperature of 99.1; right?
A. Correct.
Q. Which went up to 100.7. And then it says the child had also been not eating well for the past day when she went in; right?
A. That's what it says, yes.
Q. It says that; right? Okay. Now, this would indicate that what we just looked at, fussy all the night prior to admission and on the morning of admission which does not really come -- it's not really consistent with your testimony that she really wasn't being not normal until the morning of April 24; right?

A. It is not consistent with that, no.
Q. Okay. And that's because you didn't rely on these medical records that we just went through or the first version of events that Miss Surber gave in her deposition testimony in July of 2012; correct?
A. I think the first sheet you showed me, having worked with a lot of medical records, there are inaccuracies in them all the time. Your later document I'm pretty sure copied from the first document. It's like a game of telephone. I will in most circumstances take a mother's history about her child over what's written in a medical chart, and that is what I took for the accurate history.
Q. Yeah. The medical chart is written by a doctor, right, Dr. Snow in one instance?
A. By a doctor who's working very hard and I, you know -- I --
Q. Well, Dr. Jason, you don't know how hard Dr. Snow is working. You disregarded the medical rec -- excuse me. Let me finish. You disregarded the medical history given to the medical providers on April 24 at Sioux City, St. Luke's, and on April 26, the Children's Hospital in Omaha, Nebraska; correct?
MR. RATHKE: Objected to as argumentative.
THE COURT: Overruled.
A. I discarded the recorded history which was probably written after the fact. When you're running around with a very sick child in the emergency room, your job is to give care, and

you're not sitting down there taking a history thinking, gee, maybe some day these details are going to have some sort of major importance. So yes, I did put the mother's history ahead of the medical --

Q. Okay. And this should just be very clear about this. You didn't rely on those medical records and on Megan Surber's first deposition testimony, her original testimony before she wrote the corrections, because the plaintiff's lawyer told you not to do it. He told you not to rely on that; right?

A. What the mother said was not --

Q. No, no, no. Excuse me. You didn't rely on it.

A. I did. In addition, I relied upon her corrections and additions to that testimony.

Q. Did you do a declaration in this case on October 22 of 2012 in which you stated, of note, various records, Miss Surber's July 5, 2012, deposition, and Miss Surber's corrections and clarifications to that deposition provide differing descriptions of how Miss Surber cleaned Jeanine's formula supplies, how she prepared Jeanine's powdered NeoSure 22, and Jeanine's symptomatic progression on April 23 and 24, end quote? Did you write that in your declaration?

A. Yes.

Q. And then in that same paragraph, did you write -- and I quote -- I have been instructed to assume that these were done as described in Miss Surber's deposition corrections and

clarifications? The information provided herein are consistent with that information, and the opinions given herein are based on that information. And you did that because you were instructed to assume that they were correct and everything else was not correct because plaintiff's counsel told to you do it.
A. Well, you've added a bit there in that whole section about why. But yes, I did that because I asked the counsel and that was the instruction.
Q. Now, unlike all of the medical records at the time of the illness when the parents I'm sure are most interested in providing the most accurate information to the medical caregivers that they possibly can, okay, the rec -- the after-the-fact statements by Miss Surber in her written statement and her corrections to her deposition occurred four years later; right?
A. Correct.
Q. And she did a written statement that you relied on, and you've very forthrightly in your declaration said I'm relying on this, I've been told to do it, and her statement said the evening of April 23 was routine; right? That's what she said.
A. Well, she did. I mean, there was no doubt that Jeanine was crying that evening.
Q. Okay. And then she said in that same written statement that you relied on Jeanine ate and slept that evening just like any other night.

A. Correct.
Q. Okay. And yet you've already testified that by four o'clock in the morning Jeanine was off the wall, really, really off-the-wall whiney.
A. No, actually what I had said was that was my understanding that happened later in the morning.
Q. Okay. Well, do you want me to show you the deposition testimony from Miss Surber?
MR. RATHKE: Page 294.
Q. Starting at page 293 -- well, actually the 4 a.m. one is on -- Mr. Rathke's correct -- 294, lines 5 through 7. Uh-huh, yes, and that -- and then --
MR. RATHKE: Excuse me. I'm going to object to this as improper examination or cross-examination.
MS. GHEZZI: Refreshing her recollection. She said she didn't remember what was in the deposition, Your Honor.
MR. RATHKE: Her answer was lines 4 through 8, and that eighth line is quite important.
MS. GHEZZI: I mean, we can start from the top of the page if you'd like. I'm happy to do that, Your Honor.
THE COURT: Why don't you start over. Thanks.
BY MS. GHEZZI:
Q. Okay. Page 294. Okay. Actually if you go to the last line -- the last couple lines on 293 is the question. When did she start being whiney and fussy? And this is to the mom, Megan

Surber. Answer, she had her first bottle at nine, her next one at midnight, next one at four. Question, a.m.? Answer, uh-huh, yes. And that -- and then the 4 is when she started getting really, really off-the-wall whiney, between 4 and 9 in the morning on the 24th. You see that?

A. So the way I would interpret that is the mother is tired, she's not clear of the time. And some time between 4 and 9 a.m. she was starting to get really off-the-wall whiney.

Q. Okay. And then go to line 13, and it says -- they're talking about the 9 p.m. feeding. Then you called your mom also on the 23rd? Some time between 9 and midnight? She says yes. Okay. Did you tell your mom that she'd been crying? Yes. And so she'd been crying? Yes. And then on page 296 if you go to that --

MR. RATHKE: I don't think we had the full answer there on that cross-examination transcript.

MS. GHEZZI: We did, yes.

THE COURT: If you were speaking to me which is the only person you should be speaking to, you need to have your microphone on.

MR. RATHKE: I do.

THE COURT: So were you talking to me or talking to yourself or -- because you're not -- you don't talk to opposing counsel.

MR. RATHKE: I meant to talk to Your Honor.

THE COURT: Okay.

MR. RATHKE: I wasn't close enough --

THE COURT: What were you saying?

MR. RATHKE: And I am just asking the Court to -- pointing out to the Court that she's not giving the full transcript testimony when she's asking questions to the witness.

MS. GHEZZI: I'm sorry. I mean, her answer was, uh-huh, yes. That was the end of the answer, Your Honor.

THE COURT: Well --

MS. GHEZZI: Line 23 -- I mean line -- it's actually on line 1 on the next page.

THE COURT: Well, I don't even know what document you're referring to because --

MS. GHEZZI: I know. It's a transcript. Let me just -- let me just --

THE COURT: But under the rule of completeness, the other side has the right to have the full answer given. I don't have it in front of me, so I don't know what the full answer is, so you all fight it out among yourselves.

MS. GHEZZI: I mean, the -- the only words on line 1 which is the answer, it says answer, uh-huh, yes.

THE COURT: Now -- okay. So does plaintiff's counsel think there's more to the answer that should be read?

MR. RATHKE: Now I've lost track where she is. Where are you?

THE COURT: Well, that didn't stop you from objecting, though.

MR. RATHKE: Oh, after the uh-huh, yes. She did -- or defense counsel did read the rest of the -- of the question or the answer, so I'm fine with that.

THE COURT: You're fine with what happened?

MS. GHEZZI: Yes.

MR. RATHKE: I'm fine with that part. It was the second part that she gave the incomplete, but I --

THE COURT: Okay. Now that's real clear. You're fine with that part. What would that refer to?

MR. RATHKE: Where she gave the answer --

THE COURT: Well, wait. Let's back up. Do you have an objection? Is there actually a pending objection, or are you satisfied?

MR. RATHKE: I'm satisfied.

THE COURT: Okay. Thank you.

MS. GHEZZI: Okay.

BY MS. GHEZZI:

Q. Let me ask you this. If you were Jeanine Kunkel's treating physician on April 24, 2008, in 2008 even after her illness was diagnosed, would you believe the version of events that the mother gave at the time she was seeking medical advice for her infant either on the 24th or the 26th of April, or would you -- would you -- let me just ask you that. You would credit that;

right? You wouldn't think she was trying to not tell you the truth.
A. I would certainly not think she wasn't telling me the truth. On the other hand, when a mother has a sick child, they're not necessarily clear in what happened when.
Q. Right. But they're more clear four years later.
A. I don't know one way or the other on that.
Q. Okay.
A. I mean, for instance, here what you just read to me says she did feed her child at 9, midnight, and 4. And -- so yes, she had her feedings during the night. So that's not discrepant from what she said later on.
Q. Okay. Now, in your Pediatrics article, one of the -- you give some, shall we say, qualifications or some limitations you say. There are five limitations to this article. And your fifth limitation says, "I could not document data validity. Much information was obtained by public health investigators at the time of the illness, but some preparation and storage information was obtained in subsequent years. Parental recall may have been inaccurate or influenced by grief, stress, and/or a sense of guilt." Did you write that in --
A. I wrote that, just as I say when you're acutely in a situation and you're exhausted, that could also be inaccurate.
Q. Okay.
A. And as health department records have been inaccurate, I

see that again and again. That is just the nature of recordkeeping.

Q. So let's go briefly to how Miss Surber cleaned Jeanine's formula supplies and how she prepared the formula; right? Now, you read her deposition, so you know what she testifies to. Before she fed her baby the 3 feedings of powdered infant formula, she fed her from the 32-ounce can -- I mean, sorry, the 32-ounce container, the plastic container, of ready-to -- liquid ready-to-feed; right? It's not ready-to-feed, but it's liquid.

A. Correct.

Q. Right? Okay. And do you know how many feedings of that that she had? Have any idea?

A. I'd have to look back through my notes. At the time I calculated it, but I don't remember.

Q. And it's also true that this was -- the babies were delivered by Cesarean section as you said; right?

A. Right.

Q. Okay. And Miss Surber and Troy Kunkel, the father of the twins, knew ahead of time that they were going to have -- that the babies would be delivered by C-section; right?

A. Correct.

Q. Okay. And they scheduled an appointment to go in and have the babies delivered at that point; right?

A. Yes.

Q. And so they knew that at some point their babies were going

to come home and they'd have to be fed; right?
A. Presumably, yes.
Q. And she knew ahead of time, the mom knew ahead of time, that she was not going to breast-feed; right?
A. Correct.
Q. And when the babies went in and she delivered the babies, they -- the parents had not purchased any formula at all; right?
A. Correct.
Q. So the only formula that was available was the formula -- when Jeanine Kunkel came home that was available was the formula that was given to the -- to the mom, Miss Surber, in a bag, couple of bags, that the hospital personnel had put together for her; right?
A. Correct.
Q. Okay. And the vast majority was ready-to-feed, and there was one can of powdered infant formula.
A. Correct.
Q. Okay. So on the evening of April 23 at 9 p.m. when the baby is fussy enough, whiney and whiney, crying and crying according to the grandmother's deposition that the mother -- that Megan Surber called her up because she was concerned about it --
A. Well, the grandmother didn't describe it because she says she didn't hear the baby crying in the background.
Q. Oh, no, no, no. I'm sorry. Can I have that deposition?

I'm sorry. I forgot to do this with you. And you did mention that, so I apologize. Let me show you this.

THE COURT: So what are you showing the witness?

MS. GHEZZI: I just -- I'm just having it there in case she doesn't recall, Your Honor. I'm showing her a copy of the deposition of the grandmother. She just test --

THE COURT: Oh, yes, she's previously testified she read that.

MS. GHEZZI: Yes.

THE COURT: Okay. Thank you.

MS. GHEZZI: Okay.

BY MS. GHEZZI:

Q. So if you would please, Dr. Jason, turn to page 56, line 18. It says, question, until -- okay. Then the next paragraph -- and they're looking at an exhibit -- says -- and the exhibit that they were looking at is the grandmother's written statement -- says, I remember Megan called. I can't read that. Does it say -- Megan -- oh, I'm sorry. That's the question. And then the answer from the grandmother, Diana Terrell, says Megan called me Wednesday evening. It says eve, April 23, to say Jeanine was crying and crying. What time did she call you? Not early evening. Later evening I believe. Question, well? Answer, nine o'clock or so. Question, she called you about nine? Answer, yeah.

You see where she says she was crying and crying?

A. And she goes on to say, "Do you remember what she told you?" Just that she was fussy. She was all tensed up and upset which is very much you see with a colicky child, you know, just normal new mom stuff.
Q. And then she says, question -- and I asked a poor question. When you say she was tensed up, does it mean she, Megan, was tensed up or she, Jeanine, was tensed up? And her answer was Megan was nervous because she was crying. Quest -- question, Megan was nervous because the baby was crying? Answer, yes. Question, did she describe to you how the baby was crying? Answer, she didn't say any particular thing. She just said she was crying. Right?
A. Correct.
Q. So my question to you -- go back to this --
A. And this is where she says she couldn't hear her crying in the background. I imagine I just told her, you know, babies cry, normal baby stuff, what you'd say to a daughter who was upset.
Q. Okay. Thank you.
A. Uh-huh.
Q. So her daughter was upset, and even though she had had a baby before who was now eight years old, she was upset enough to call her mother at nine o'clock at night; right?
A. Would you not do that with your mother?
Q. My mother died when I was 15, so no.

A. I think if she had lived you would have done that.
Q. Okay. So with the boiling of the water, according to the contemporaneous record that was made by the investigator from the Nebraska Department of Health and Human Services who talked to her by phone, Megan Surber told the investigator that she boiled water to make the formula and then she mixed the formula with the water and then she boiled it again and then she cooled it down before feeding the baby at 9 p.m. and 12 midnight and 4 a.m.; right?
A. She did say that, yes.
Q. And you disregarded that record; right?
A. I took her correction of that record.
Q. Right. And the correction -- and her correction to that record which was also four years after the fact which was fine is that she boiled water and cooled it down and then put it in to mix the powdered infant formula; right?
A. Correct.
Q. Okay. And although you didn't -- you didn't credit her testimony -- not her testimony but you didn't credit her report to the state investigator when she said I boiled it again with the formula in there, you did credit her testimony when she said I boiled the water every time I made formula; right?
A. Well, part of the reason I didn't credit the part about boiling the formula is I have boiled formula, and I don't think she could have handled it if she did what she described. But

yes, I did take her later statement.
Q. Okay. But that was also part of your declaration in this case in October 2012 where you said in terms of how the formula was prepared I was asked to assume that what Miss Surber said four years later was the truth and not what she told the investigator; right?
A. Correct.
Q. And if she had boiled the water and then she had put it in the formula with the powdered infant formula in it and then she had brought that to a boil, there could not possibly be any E. sak in it; right?
A. That's correct.
Q. Because that boiled water would have killed E. sak in less than a second.
A. Yes, that's correct.
Q. Okay.
THE COURT: Would now be a good time to break?
Members of the jury, that will conclude the evidence for today. Remember keep an open mind till you've heard all of the evidence. And we'll see you back here tomorrow morning at 8:30. Thank you.
Oh. And don't read anything in the newspapers. I think there was another article today, so we'd ask you not to read that. Don't allow anybody to tell you about it. I haven't seen it, but don't allow anybody to tell you about it. Thank

you.

(The jury exited the courtroom.)

THE COURT: Dr. Jason, you may step down.

So are we on schedule, counsel?

MR. RATHKE: Your Honor, we are behind schedule, but I'm going to make some adjustments to do my darnedest to catch up.

THE COURT: Okay.

MR. RATHKE: I still am optimistic that we would be able to rest about half of Monday.

THE COURT: Yeah. Which Monday might that be?

MR. RATHKE: I'm shooting for next Monday.

THE COURT: I'm pretty confident it's 2014. I'm just not confident which Monday. Okay.

MR. RATHKE: But I understand the Court's concern, and I'm going to cut, slash, and burn.

THE COURT: You know, it's not so much a con -- it's not a personal concern for me. It's for the jury because I consulted with the lawyers. I relied on that, and I told them. So I don't like lawyers making a liar out of me which is what looks like is going to happen. And I also have this patent case. I kind of think it might settle, but there's been no indication that the lawyers are thinking what I'm thinking. So I assume that's going to trial a week from this coming Monday. And so I might have to bump that. I guess it's Tuesday because

Monday's a holiday.

Okay. Why don't you be seated. I've gotta get going because I have to give my court reporter a break because we start sentencings at three o'clock. But I'm a little bit concerned -- and maybe I'm just not understanding what's going on -- about this questioning about declarations you gave because even though a declaration is under oath and all, the declaration that this witness gave is hearsay. So it's not admissible.

And just like when you start asking -- and I mean lawyers in general -- start asking questions about you said in a deposition and they're getting into what they said in a deposition or what they said in a declaration, you can't ask that unless you're using it to impeach the witness with a prior inconsistent statement.

And I -- maybe I'm just not smart enough to figure out what was going on because with all due respect, you know, you had probably over a thousand objections to the form of the questions in the depositions you were defending. I ought to be interposing objections to the form of the questions because they're compound, confusing, vague, and all that.

But I don't understand what you're doing because it didn't seem to me you were doing it for impeachment. You were doing it to get her to acknowledge what she said in a declaration, and that's improper. There's no theory of evidence that allows that form of questioning that I'm aware of. You can

do it for impeachment, but you can't get them to acknowledge what they said in a prior statement because what they said in a prior statement is hearsay.

MS. GHEZZI: Right.

THE COURT: So is that what you were doing, or were you using it for some other -- were you using it for impeachment?

MS. GHEZZI: I was using it for impeachment, Your Honor.

THE COURT: Okay.

MS. GHEZZI: We call it a declaration. I mean, it's a -- when they do a report, they do it as a declaration, so she did a supplemental report.

THE COURT: Okay. And you were using her prior -- it doesn't even have to be a declaration. It can be any -- you were using some prior written statement of hers for impeachment.

MS. GHEZZI: Right.

THE COURT: But that isn't what -- I'll take you at your word that's what you were doing. It seems to me you were trying to get her to acknowledge the prior statement just to get her to acknowledge it so you're kind of putting it in as substantive evidence because what you need to do is ask her something under oath now; and then if it's inconsistent, you can obviously impeach her with the declaration, the report, anything in writing that she did, her article, anything.

So as long as we're clear that that's what you're doing, I assume I misunderstood what you were doing which could easily happen because I'm a multi-tasker. So -- but as long as we're clear, you can do that for impeachment purposes, not as substantive evidence, there's no problem.

MS. GHEZZI: Absolutely. Thank you, Your Honor.

THE COURT: Okay? Thank you. Thank you. Anything we need to take up? Okay. I'd like to see the lawyers at 8:00 tomorrow morning, so why don't you be here at 8, and then we'll start at 8:30. Thank you.

MS. GHEZZI: Thank you, Your Honor.

(The foregoing trial was adjourned at 2:34 p.m.)

CERTIFICATE

I certify that the foregoing is a correct copy of the transcript originally filed with the Clerk of Court on 3-20-14 incorporating redactions of personal identifiers and any other redactions ordered by the Court in accordance with Administrative Order 08-AO-0009-P.

S/Shelly Semmler
Shelly Semmler, RMR, CRR

4-29-14
Date

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